Design and cultural adaptation of an e-mental health intervention for depression

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DESIGN AND CULTURAL ADAPTATION OF AN E-MENTAL HEALTH INTERVENTION FOR DEPRESSION

LE DÉVELOPPEMENT ET L'ADAPTATION CULTURELLE D'UNE INTERVENTION PSYCHOLOGIQUE EN LIGNE POUR LA DÉPRESSION

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• Poster presentation: Geneva Health Forum. 2016. Cultural Adaptation of Self-help [including E-Mental Health] Interventions for common mental disorders. Geneva, Switzerland. 20th April 2016.

• Poster presentation: Harper Shehadeh M. 2017. Step-by-step (خطوة خطوة): Feasibility testing an e-mental health intervention in Lebanon. 9th Conference of the International Society of Research on Internet Interventions. Berlin, Germany. 12th October 2017.

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Chapter 1

Outline and Abstract

Outline

Thesis outline

To fulfil its research aims, this thesis employs mixed methodologies, including systematic review and meta-analysis, qualitative research and pre-post design empirical testing. This comprises the in-depth formative work for the Step-by-Step intervention, prior to the fully-powered randomised testing that is currently being undertaken in Lebanon and elsewhere.

Chapter one provides a summary of the work and findings in both English and French, as required by the course handbook. Chapter two is a general introduction, providing background information on the problem and research questions. Chapter three is an article on the qualitative results from a person generated outcome measure used in Pakistan and Kenya, analysing and comparing the self-reported major life problems of participants in two diverse contexts and comparing them to items used in Western-style outcome measures for mental health. Chapter four presents a systematic review and meta-analysis on the extent and effect of cultural adaptation on self-help psychological interventions. Chapter five is a publication on the concept of a WHO internet-delivered brief intervention for depression (named Step-by-Step), which is the subject of all subsequent thesis chapters. Chapter six is two publications, detailing cultural adaptation techniques and results when adapting said intervention for Lebanon and Macau. Chapter seven is a recently published article which details the experience and lessons learned during a feasibility trial of Step-by-Step in Lebanon. Chapter eight details the PhD candidate's methodological contributions to the different stages of the thesis work, with chapter nine presenting an overview of results and a discussion of the findings, which includes limitations, implications for global clinical and research practice and suggestions for future research. Finally, the overall conclusions of the entire PhD project are presented in chapter 10 of the thesis.

Abstract

Introduction

Mental illness accounts for one-fifth of all disability worldwide, with depressive disorders ranking as the third most disabling health condition globally and featuring in the top ten causes of disability in all countries. With 1.8 billion people living in fragile contexts in low and middle income countries where up to 96% of people who need mental health care do not get access to it, the scale of the problem is immense. The World Health Organisation (WHO) guidelines recommend psychological interventions for the treatment of depression, either delivered traditionally (face-to-face) or through self-help or minimally guided self-help formats. In response to treatment barriers, WHO has designed and is testing Step-by-Step, an internet-delivered, five session minimally guided intervention for depression.

There are several unresolved controversies regarding the cross-cultural validity of models and approaches to mental health nosology, measurement and treatment. This means that simple export of a self-help intervention like Step-by-Step may not be appropriate to adequately respond to local mental health needs. In order to maintain a person-centred and respectful approach to care, local problems and treatment priorities should be part of tailoring, adapting and evaluating psychological interventions. Evidence suggests that sensitive adaptation can increase efficacy of an intervention. Once an intervention is adapted, its safety and efficacy must be adequately studied, before promoting large-scale use in the population. Pilot testing could be particularly important in diverse or complex contexts to ensure that the intervention, its delivery and the efficacy research methodology are acceptable and feasible.

The objectives of the PhD work were: to design an e-mental health intervention for depression to be used globally; to illustrate the need for contextual adaptation of evidence-based interventions and their evaluation methods; to adapt the Step-by-Step intervention for testing and scale-up in Lebanon and Macau; and to carry out feasibility testing to inform research methods in subsequent project phases. In this doctoral thesis, I aim to highlight the importance of local adaptation of complex interventions in health, and to share considerations and experiences of designing and adapting a scalable mental health intervention for testing in Lebanon.

Methods

We used mixed methodologies in order to reach our objectives. In chapter three we report the use of data gathered as part of a randomised controlled trial (RCT) of a psychological intervention in Kenya and Pakistan. The psychological outcome profiles questionnaire (PSYCHLOPS) was delivered to participants via an interview as part of the battery of RCT measures pre- and post-intervention. The elicited free-responses were analysed thematically and frequencies reported.

In chapter four we describe the methods and report the results of a meta-analysis, based on a systematic review that also included data collection about cultural adaptation methods employed by the authors of the included primary studies. Further, we developed a simple scale to assess the extent of adaptation in each study, and used the ensuing scores in meta-regression analyses to assess whether adaptation could explain the effect size of a given intervention.

Chapter five details the design process and considerations employed when creating Step-by-Step. Two papers that focused on cultural adaptation are reported in chapter six, which entails the qualitative research methods used to gather information necessary for making revisions to the Step-

by-Step intervention. Finally, chapter seven is a research paper on the uncontrolled pilot test of the acceptability of the intervention and the feasibility of a future large-scale trial. We report descriptive statistics (t-tests and Wilcoxen signed ranks) on the outcome measures (depression - PHQ-8, anxiety - GAD-7, wellbeing - WHO-5, disability - WHODAS and self-perceived problems - PSYCHLOPS), and the process evaluation interviews we conducted with intervention completers, drop-outs, study staff, and clinic managers. Finally, we describe the thematic analysis conducted on these interviews, and describe the results according to the semi-structured interview schedules.

Results

We found that in both Kenya and Pakistan, the responses to the open-ended questions of the PSYCHLOPS questionnaire pertained to self-perceived problems that were not covered in the other nomothetic, diagnostic-based outcome measures used in the trial.

With our systematic review, we found that only very limited information is usually reported by the authors of the primary studies about the process of cultural adaptation of self-help interventions at the local level. Of the 3886 studies screened for inclusion, we included eight randomised controlled trial studies of self-help interventions in the meta-analysis (four on e-mental health interventions and four on bibliotherapy). The pooled effect size (standardised mean difference) of the interventions was -0.81 (95% CI -0.10 to -0.62) with low to moderate heterogeneity between the studies (I^2=28.9%, p=0.188). More adaptation points was associated with a higher effect size. Using the assigned adaptation score of each study in the meta-regression we found that a one-point increase in the adaptation score of a study was significantly associated with an increase in standardised mean difference of 0.117.

Step-by-Step was structured as a five-session, behavioural activation intervention for depression to be delivered through smartphones, tablets or computers. It was designed with the option of a non-specialist support person to accompany the user through the intervention via up to 15 minutes phone or text-based support sessions.

In adapting Step-by-Step for use in Lebanon and Macau, contextual and cultural adaptations were made. These included the identity of the main helping character (a doctor in Lebanon and a community elder in Macau); revising politically reminiscent illustrations; updating positive and negative coping behaviours and activities to be more representative; changing the names and appearances of characters; simplifying text and removing repetition; and using a local idiom of distress “tired psyche” in Lebanon.

Finally, in the pilot study, Step-by-Step showed promising results: completing Step-by-Step lead to statistically significant, clinically positive changes on all outcomes. Overall, the intervention was accepted and process evaluation interviews with users, drop-outs and other key stakeholders provided information which will impact future testing and use of Step-by-Step.

Discussion

The qualitative results based on the PSYCHLOPS questionnaire in Kenya and Pakistan suggest that a Western only model of mental distress does not capture important local features relevant to informing the design and conduction of efficacy studies of interventions for common mental disorders. Compounding this finding, we also found that local adaption of self-help psychological interventions can contribute to increased intervention efficacy. Though the study could not demonstrate the causality of this finding and was limited by pooled sample size, adaptation may be nonetheless potentially interesting for service planners. Systematically carrying out cultural adaptation was crucial, as many changes were made to Step-by-Step through our thorough

adaptation process with local actors. The feasibility testing of Step-by-Step provided valuable information to inform the design and conduct of a future large-scale efficacy trial and that Step-by-Step is a potentially promising intervention for reducing the symptoms of depression. The research contributing to this PhD work carried various limitations, therefore cautious interpretation of some of our results is necessary.

Conclusion

Tailoring the selection of therapy to local problems and treatment goals, as well as adapting the intervention to the local context and culture should be considered by service managers and clinicians working in diverse settings. An adapted, minimally guided, internet-delivered intervention like Step-by-Step could help close the treatment gap for depression if integrated responsibly into an existing care system.

Résumé

Introduction

Les troubles mentaux constituent un cinquième de la charge mondiale de morbidité. Les troubles dépressifs se classent au troisième rang des problèmes de santé les plus invalidants au monde et figurent parmi les dix premières causes d'incapacité dans le monde. Actuellement 1,8 milliard de personnes vivent dans des contextes sociopolitiques précaires dans des pays à faibles et de moyens revenus où plus de 90% des personnes ayant des besoins de soins en santé mentale n'y ont pas accès. L'ampleur du problème est donc immense. Les lignes directives de l'Organisation Mondiale de la Santé (OMS) pour le traitement de la dépression recommandent en première intention une prise en charge psychologique, soit de manière classique en face à face, soit au moyen d'une intervention à distance guidée ou en auto-assistance. Pour faciliter l'accès aux soins de la dépression, l'OMS a conçu « Step-by-Step », une intervention délivrée par internet, comprenant cinq séances et guidée à distance par un intervenant non-spécialiste.

L'universalité des modèles, des approches et des outils de mesure en santé mentale étant questionnable, la simple exportation d'une intervention psychologique telle que Step-by-Step pourrait ne pas répondre de manière adéquate aux contextes et aux besoins locaux. Afin de garantir une approche de soins respectueuse et centrée sur la personne, les interventions psychologiques et leurs évaluations doivent être adaptées aux problématiques locales. La littérature scientifique appuie ce point en suggérant que l'adaptation peut accroître l'efficacité d'une intervention psychologique. Les études d'efficacité sont indispensables pour garantir la pertinence clinique d'une intervention avant son utilisation à grande échelle. En effet, la conduite d'études pilotes semble particulièrement importants dans des contextes complexes ; ceci afin de garantir que l'intervention, sa modalité d'application et la méthodologie pour la tester sont acceptables et réalisables.

Les objectifs de ce doctorat ont-été : 1., de concevoir une intervention pour la dépression délivrée par internet et applicable dans le monde entier, 2., de démontrer la nécessité d'adapter les interventions psychologiques basées sur des données probantes ainsi que leurs méthodes d'évaluation au contexte 3., d'adapter l'intervention Step-by-Step aux contextes spécifiques du Liban et de Macao et 4., d'évaluer la faisabilité de piloter une étude d'efficacité dans ces contextes et ainsi préciser les méthodes de recherche dans les phases ultérieures du projet. En résumé, le but de ce travail de thèse est de partager notre expérience de la conception d'un outil d'intervention de santé mentale délivrée à distance ou en auto assistance, de son adaptation et de l'étude d'évaluation préliminaire de Step-by-Step à un contexte complexe comme celui du Liban.

Méthodes

Nous avons utilisé une méthodologie mixte afin d'atteindre les objectifs du doctorat : une revue systématique de la littérature, complémentant des études quantitatives et qualitatives. La première étude (chapitre 3) analyse des données recueillies dans le cadre d'un essai contrôlé randomisé (ECR) évaluant l'efficacité d'une brève intervention psychologique au Kenya et au Pakistan. Le questionnaire « Psychological Outcome Profiles (PSYCHLOPS) » a été remis aux participants lors des entretiens avant et après l'intervention, et les réponses obtenues ont été analysées par thème et par fréquence.

La deuxième étude (chapitre 4) est une revue systématique de la littérature, une méta-analyse et l'évaluation des méthodes d'adaptation culturelle employées. L'effet d'adaptation culturelle sur

l'efficacité d'une intervention a été déterminé grâce a une méta-régression.
Le chapitre cinq détaille le processus de conception et les différentes considérations prises en compte lors de la création de Step-by-Step.
Les deux articles sur l'adaptation culturelle (chapitre six) ont utilisé des méthodes de recherche qualitatives ; l'objectif était de recueillir l'information nécessaire à la révision de l'intervention Step-by-Step. Enfin, le chapitre sept décrit une étude pilote non contrôlée effectuée à très petite échelle pour évaluer l'acceptabilité de l'intervention et sa méthodologie d'évaluation. Nous y rapportons des statistiques descriptives sur les mesures d'effet (dépression - PHQ-8, anxiété - GAD-7, bien-être - WHO-5, incapacité - WHODAS et auto-évaluation de ses problèmes - PSYCHLOPS), et des entretiens auprès des participants, du personnel de l'étude et aussi des abandons. Finalement, nous décrivons les processus d'analyse des données issus des entretiens et présentons les résultats par thématiques).

Résultats

Les principaux problèmes relatés par les participants au questionnaire PSYCHLOPS n'étaient pas représentés dans l'ensemble de mesures nomothétiques et diagnostiques utilisées dans l'étude.
Notre revue systématique révèle que les études primaires ne font peu ou pas du tout mention des méthodes d'adaptation culturelle d'interventions d'auto-assistance au niveau local: sur les 3886 études examinées et incluses dans la méta-analyse, huit sont des études contrôlées randomisées portant sur les interventions d'auto-assistance (quatre sur la santé mentale et quatre sur la bibliothérapie). La taille de l'effet réuni (différence moyenne standardisée) des huit études incluses était de -0,81 (IC à 95 % : -0,10 à -0,62) avec une hétérogénéité faible à modérée (i^2 28.9%, p=0.188). En utilisant le score d'adaptation attribué à chaque étude dans la méta-régression, nous avons constaté qu'une augmentation d'un point du score était significativement associée à une augmentation de la taille de l'effet (différence moyenne standardisée) de 0,117.
Step-by-Step a été conçu comme une intervention d'activation comportementale pour la dépression en cinq séances, qui est offerte à l'aide d'un smartphone, d'une tablette ou d'un ordinateur. L'intervention peut être délivrée avec ou sans le soutien d'une personne non spécialiste qui guide l'utilisateur pendant l'intervention au téléphone ou par chat au maximum 15 minutes par semaine. Des adaptations contextuelles et culturelles ont été apportées pour l'utilisation de Step-by-Step au Liban et à Macao. Ces adaptations couvrent de nombreux aspects spécifiques, dont l'apparence, les comportements et les activités de personnages. Au Liban, l'utilisation du langage local de détresse "psyché fatigué" a été ajouté.
Enfin, l'essai pilote non contrôlé avec Step-by-Step s'est avéré prometteur : l'utilisation de Step-by-Step a entraîné des changements cliniques significatifs sur toute les mesures de santé mentale. Dans l'ensemble, l'intervention a été acceptée. Les entretiens d'évaluation auprès des participants et du personnel d'e l'étude ont fourni des informations pertinentes qui permettront poursuite d'essais cliniques de Step-by-Step dans le futur.

Discussion

Les résultats basés sur les réponses au questionnaire PSYCHLOPS au Kenya et au Pakistan ont montré que le modèle occidental de la détresse mentale ne reflétait pas les préoccupations locales pertinentes, lesquelles doivent être prises en compte lors de la conception et la mise en œuvre des études d'efficacité. Nous avons constaté que l'adaptation des interventions psychologiques d'auto-assistance, lorsqu'elles sont utilisées dans divers contextes culturels, peut accroître leur efficacité. Bien que cette étude, limitée par la taille de l'échantillon, ne démontre pas la causalité de ces

résultats, l'adaptation est potentiellement intéressante quand une intervention est utilisée à grande échelle. La pertinence des changements apportés, lors de la phase d'adaptation de Step-by-Step a démontré l'importance de procéder systématiquement à l'adaptation culturelle, de cette intervention. L'étude de faisabilité de Step-by-Step a entrainé d'importantes révisions dans la conceptualisation de la recherche et l'intervention à large échelle et elle indique que Step-by-Step pourrait réduire l'intensité des symptômes psychopathologiques. Les recherches qui ont contribué à ce doctorat comportent des limitations, donc les résultats doivent être interprétés avec prudence.

Conclusion

Les gestionnaires de services et les cliniciens travaillant dans des contextes divers devraient envisager d'adapter le type et le contenu d'une intervention thérapeutique aux besoins exprimés par la communauté. Une intervention comme Step-by-Step, adaptée et guidée à distance par un intervenant non-spécialiste, pourrait aider à réduire l'écart de traitement pour la dépression, si celle-ci est intégrée de façon responsable dans un système de soins existant.

Chapter 2

Introduction

Introduction

Global burden of mental health disorders

Figures from the Institute of Health Metrics and Evaluations estimate that mental illness accounts for one-fifth of all disability globally (22.7% of all years lived with disability (YLDs) (1)). These estimates are even argued to be overly conservative. When also considering disability due to self-harm or certain neurological conditions, mental illness is estimated to represent one-third of global disability (2). Compounding their burden is the fact that mental illness onset tends to be early in life and can be serious and enduring (3), thus affecting educational attainment, job prospects and family life over the lifespan. Compared to most other non-communicable diseases, this combination of early onset, high prevalence and long duration makes mental disorders particularly and uniquely disabling. Depressive disorders are particularly burdensome, ranking as the third most disabling health condition globally (4) (almost 10% of all YLDs), and featuring in the top ten causes of disability in every country (5). In addition, depressive disorders not only affect the individual, but have far-reaching negative personal and economic effects at family, workplace, community and societal levels (6).

Mental disorders are linked to disadvantage and stressors such as insecurity or social or economic adversity (7,8) through a complex association. Social causation theory posits that, compared to people who have higher socioeconomic status (SES) those who have lower SES are more likely to experience mental disorders (and other health problems), and that this is true across the life course (9). Conversely, the social selection or social drift theory claims that mental health problems can negatively affect socioeconomic advancement, including educational attainment and job opportunities (10,11). Several indicators of SES exist, including those that aim to capture material wealth, living under the poverty line, number of rooms per person in the home, personal and familial education level or occupational attainment, but also ethnicity, sex and gender (9). Other more abstract phenomena are also used to gage SES, such as social support, knowledge and behaviours, and social capital (12). Importantly, the link between unfavourable SES and poor mental health is likely bidirectional, whereby both social causation and social selection mechanisms coexist and reciprocally perpetuate (10). Put simply, the less material wealth, education or job success one has, the more likely a person is to suffer from mental disorders, and vice-versa. Some studies exploring this reciprocity show that social causation is more important in health and mental health attainment (13,14). A recent study in South Africa and one systematic review from 2015 found that the two mechanisms are fairly equal, though the link is nuanced depending on the SES measures used (12,15).

Migration and instability can compound other socioeconomic risk factors for mental health problems, for example, among economic migrants, prevalence rates of depression have been found to be up to 20% as opposed to 10.8% global prevalence (16,17). Studies estimating depression prevalence among Syrian refugees in (high income) host countries have found depression prevalence rates of up to 44% (17–19), likely linked to loss, trauma and pre-and post-migration stressors as well as downward social mobility on arrival (20). In 2016, 24% of the world's population, or 1.8 billion people, were living in fragile contexts, such as poverty, conflict, violence or other social, political or economic instability (21). Living in fragile contexts puts people at higher risk of developing

depression and other mental disorders, and all states of fragility are in low or middle income countries where access to treatment for mental illness is limited.

The vicious cycle of depression and social and economic disadvantage may be broken by combining interventions that combat social causation with interventions that target poor mental health, termed psychosocial interventions (10).

Responding to the treatment gap with scalable interventions

The treatment gap for mental health disorders is vast. It is estimated that 80% of people who have major depression in high income countries (HIC), and up to 96% in low and middle income countries (LMIC) do not get evidence based treatment for these highly disabling conditions (22). Unfortunately, over the last decade, this treatment gap has not significantly reduced. The identification of barriers and opportunities to reduce the mental health treatment gap through a Lancet commission (23), three Lancet series on global mental health (2007, 2011 and 2018) and all WHO member states signing up to the WHO mental health action plan 2013-2020, have little contributed to produce real-world changes. Worldwide, the population's mental health needs remain largely unmet (24). As conditions that largely contribute to disability, mental disorders should feature high as a priority for health systems to address (1).

There are a number of reasons for people not getting the diagnosis and the quality treatment they need, including geographical barriers; out of pocket care costs; stigma and poor knowledge about mental health; medication supply issues; and low prioritisation of mental health in national policy and health care funding streams, all contributing to the *"scarcity, inequity and inefficiency"* formula (25). While the burden of mental disorders is over 20% of all global disability, most countries allocate less than 5% of often inadequate overall health expenditure to mental health (26). Furthermore, access to care is highly inequitable and highly socially determined (16,18).

Other major reasons for the limited availability of care are the lack of mental health care providers and inadequate training in mental health of the general health workforce (26). In the African region, there are less than 0.9 mental health workers per 100,000 population, compared to 50 in the European region. In HIC, there are an average of 9 psychologists and 12 psychiatrists per 100,000 population, with this figure much lower at 0.05 and 0.06 respectively in low income countries. There is also wide disparity in the numbers of psychiatric nurses available to people with mental disorders. While numbers of psychiatrists are rising in HIC, in LMIC, the numbers have been unchanged since 2011 (26). Closing the treatment gap will be a challenge and one that requires response from the political down to the community level. Concerted multi-sectoral actions should actively involve stakeholders across health- and non-health related sectors of society, such as education, justice and social services, increasing the promotion of mental health and appropriate treatments for mental illness.

Evidence compiled as part of WHO guidelines for the treatment of depressive disorders suggests that antidepressants may not be superior to psychological treatment, with adverse effects being more

likely with antidepressant treatments compared to non-pharmacological interventions[1]. The WHO recommendation encourages psychological treatments as a first line therapy in non-specialist healthcare settings (29). Because psychological treatments include a broad array of interventions and techniques, a further recommendation specifies the following brief psychological interventions specifically: Interpersonal therapy; cognitive behavioural therapy; and problem-solving treatment (if there are sufficient human resources) (30). However, psychological treatments are more resource-intensive than anti-depressants, because of the number of sessions required and their being face-to-face (needing more human resources). The WHO guidelines are intended for resource-restricted settings and do acknowledge the high resource intensity of psychological interventions, as well as potential issues with medications supply. A further consideration is that local adaptations and careful planning for the scale up of interventions are necessary, but overall, there is robust evidence that mental disorders can be treated effectively using non-pharmacological interventions as first line therapy.

Psychological interventions are traditionally provided by a psychologist or other mental health specialist. However, non-specialists, or even non-health workers can be trained and supervised to provide effective, brief psychological interventions for depression (31–33) using a task-shifting approach. Task-shifting is where specific tasks are appropriately delegated to health workers with shorter training and fewer qualifications (34). Even clinical supervisory roles can be partly assumed by non-specialists, using peer supervision systems, further reducing resource intensity (35). Task-shifting approaches are used in HIC and LMIC alike, across the spectrum of health care interventions and are also endorsed by WHO as a major tool in increasing access to healthcare when carried out responsibly (34,36,37). Further to task-shifting, self-help delivery formats (treatment driven by the beneficiary alone with the aid of a book or other therapeutic resource) are recommended as an even less resource intensive way to deliver therapeutic content of psychological interventions where human resources are lacking (38).

With the understanding that psychological therapies are effective and safe but that many settings are under-resourced, WHO has designed and is testing a suite of “scalable” psychological interventions to increase access to evidence based psychological interventions (39). The characteristics of a scalable psychological intervention are outlined in table 1 and include quality, applicability to comorbid cases or undiagnosed presentations, delivery by non-specialists, brevity, simplicity, adaptability and innovation in delivery. All of these elements result in less reliance on specialist human resources for higher treatment coverage.

Table 1 outlines the ways in which scalable interventions reduce the need for specialist human resources and could help health systems reach the goal of universal (mental) health care coverage. At the crux of the universal health coverage movement is equity and accessibility. While some modes of delivery of scalable psychological interventions may have limitations in terms of equity, they may make up for these limitations in terms of the coverage they can achieve.

Table 1. Characteristics of scalable psychological interventions (39)

[1] In fact, in a recent systematic review, it was found that psychological interventions work for depression all over the world, but that effectiveness is greater in Low and middle income countries (LMIC) than in high income countries (HIC) (28)

Evidence-based	Scalable interventions should be based on therapeutic modalities that have a clear theory of change and have demonstrated effectiveness in robust efficacy studies.[2]
Transdiagnostic	With scalable interventions, there is no need for a formal diagnosis in order to obtain access to the therapy. Alternatively, a scalable intervention could be provided to anyone presenting with psychological distress or who has responded to a symptom severity or disability severity checklist and reached a certain cut-off score set by the implementing service. This saves on human resources because no specialist diagnostic interview or test is required. Also, many people suffer with mixed anxiety and depression for example, so in order to remain inclusive of those with comorbidities, scalable interventions are not contraindicated for any mental disorder and should be safe for all to use.
Non-specialist delivered	Non-specialist health workers and lay community health workers can provide scalable interventions with appropriate training and ongoing supervision. There should also be some means of quality monitoring, support (such as peer support or supervision sessions) and all task-shifting should be done keeping in mind the workload of the health worker and with proper remuneration. Non-specialist training should include when it is necessary to refer people in need of more specialist support for safety reasons.
Basic	The content should be easy to understand by non-specialist health workers and the beneficiaries of the intervention.
Brief	Psychological therapies can vary in their length. More than 10 sessions may be unfeasible in many contexts. 5-8 sessions is likely to be optimal in order to deliver content and ensure that people can attend and keep up with sessions.
Easily culturally and contextually adaptable	For an intervention to work in many settings and contexts, it should be written and produced in such a way that it can be adapted to a range of languages, cultures and health care contexts. By way of a manual that is revised for different contexts, fidelity to the basic content can be retained. This may mean writing content as devoid of cultural references as possible, which can then be added locally. Using clear language is important to aid translation and delivery should be feasible in many contexts.
Individual or group	Delivering an intervention to a group means that one can reach more people and also benefit from the dynamics and collectivism of the group itself, though it may be more accepted socially or culturally to deliver the intervention one to one.

[2] Such as WHO recommended interpersonal therapy, cognitive behavioural therapy and problem solving (for depression). Having a manual and standard training materials can help to maintain fidelity to the intended evidence-based intervention.

Use of guided or unguided self-help	Self-help therapies may be less effective than face-to-face therapies, but guided self-help (where a helper contacts the client throughout the intervention to offer support) has been shown to be similarly as effective as face-to-face interventions (40). In both cases, self-help can reduce the need for specialist human resources for mental health. Unguided self-help yields low effect sizes in comparative studies, but implementing it at scale could increase the reach to still provide a cost-effective solution in terms of public mental health(38).
Client is provided tools to self-manage their symptoms	Enabling the beneficiary agency in their recovery and beyond is key. By teaching a client skills and healthy coping mechanisms, they can then promote their own recovery in the present and future, and make progress in other life domains, e.g., having learned problem solving skills.

Figure 1. Depiction of how scalable interventions may improve access to evidence-based mental health care.

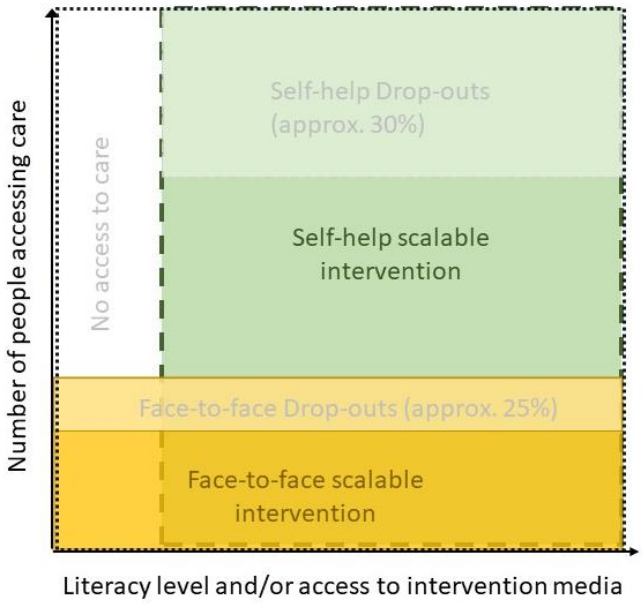

Figure 1 is a visual representation of how providing both a face-to-face scalable intervention and a self-help scalable intervention could mean that most of a population needing mental health care could theoretically access a psychological intervention. The x-axis is one's ability to access mainly written or multimedia-delivered content, and the y-axis is how many people can access care. The area of the figure is the proportion of people needing access to care. Note how, despite many people not being able to read, afford the internet or have access to their own multimedia device, the two delivery models (face-to-face and self-help) combined potentially cover most of the population in need, and though many people drop out of treatment, they were at least *able* to access it.

Scalable interventions therefore hold great potential as public health interventions for high-burden mental disorders. Of course, strengthening a mental health care system to be able to identify,

provide the care for and follow up potential users is an enormous but not impossible task not covered in this thesis.

In a perfect service integration example, self-help may be used as step one of a stepped care model either accessed through health services or self-sign up. In this example, self-help represents the first low-cost and low resource-intensive step in the care journey (therefore available to a high volume of beneficiaries), with those needing more intensive or specialist care (fewer cases) being referred to subsequent, more concentrated steps if self-help didn't improve their (monitored) symptoms (41). Self-help via internet or bibliography delivery should improve accessibility to those who face geographical barriers to care or stigma in seeking mental health care as an active and low-cost alternative to people being held on a waiting list. Some users will manage the intervention well, and their symptoms will improve. Others will remit naturally (42), and some will drop out (43,44) due to low motivation or symptom improvement (as is the case with many health interventions). For those who are less literate, cannot afford access to multimedia content or whose distress or disability are severe, they may skip the first, self-help step and be stepped straight to a face-to-face intervention. This means that human resources are efficiently allocated according to need.

The first WHO scalable mental health interventions

The first WHO scalable intervention for mental distress to be conceptualised and tested was Problem Management Plus (PM+) (45). It is a five session group or individual, face-to-face, manualised intervention which addresses psychological distress using problem-solving plus behavioural activation techniques. Problem solving therapy teaches problem solving skills and applies them to the client's life problems that appear to be affecting their mental health (46). Behavioural activation uses positive reinforcement through engaging the client in rewarding activities or constructive activities that clients may have been avoiding, through scheduling such activities into the client's life (47). PM+ has been shown to effectively improve symptoms of depression and anxiety and increase wellbeing when delivered by briefly trained lay persons (33) and non-specialist health workers (48) in Kenya and Pakistan. The group version is currently being tested by WHO and its partners, with positive preliminary results in Nepal and Pakistan.

In addition, PM+ was also adapted for use with young people, with the creation of Early Adolescent Skills for Emotions (EASE) (49), a brief group intervention based on emotion regulation, behavioural activation and problem solving techniques with both adolescents (seven sessions) and their caregivers (three sessions). EASE is currently being tested in RCTs in Lebanon, Jordan, Pakistan and Tanzania.

A further WHO scalable intervention is Self-help Plus (SH+), a multimedia intervention specifically designed for humanitarian settings with particularly stark human resources and for areas where literacy levels may be low (50). SH+ is designed to improve symptoms of common mental disorders and comprises a short self-help picture book, with little text, accompanied by a digital audio file. It is based on acceptance and commitment therapy, where rather than focusing on behaviour change or problem solving (as some people in humanitarian settings have little agency over their behaviour or circumstances), it focuses on changing cognitive appraisals (the way one thinks about their circumstances) and mindfulness (bringing one's attention to the present to stop the cycle of unhelpful thought rumination) as coping techniques. The intervention is typically delivered through

five sessions with up to 30 people in a room using a sound system with one support person who is briefly trained to also recognise and refer cases of high distress. A feasibility study in Uganda (ahead of a current large RCT) showed it to reduce distress and increase wellbeing on a small sample of refugees (51).

Innovation in delivering scalable interventions: e-mental health

As mentioned previously, the internet is one innovative delivery strategy that has the potential to vastly increase care coverage. While we may consider access to technology as inequitable, the world is becoming more and more connected, as shown by recent International Telecommunications Union figures. In 2018, 3.9 billion people globally were using the internet (52). This represents enormous opportunity for public health. E-mental health, that is mental health care delivered through computers, tablets or smartphones, is now being used in a number of national health systems to increase care coverage. For example, in the United Kingdom, 48 different accredited apps can be accessed nationwide as part of the National Health Service "Improving Access to Psychological Therapies" campaign (53). Australia has a national e-mental health strategy (54) and 14 government-recommended apps, while the Netherlands, since 2013, has a government funding stream exclusively for e-mental health (55). This move towards e-mental health is not just limited to high income countries: Lebanon, a middle income country with extremely stretched mental health resources, also makes reference to e-mental health as a delivery strategy in its national mental health plan (56).

Step-by-step is a new WHO e-mental health intervention currently being tested in large trials in Lebanon and in a number of sites in Europe and Egypt with Syrian refugees as part of the European Union Horizons 2020 project. Step-by-step is brief (5 sessions), evidence based (predominantly behavioural activation), transdiagnostic (potentially effective in improving symptoms of anxiety and depression and wellbeing), and is minimally guided should users or implementers choose to offer weekly telephone or written guidance from a trained "e-helper" throughout the intervention. E-helpers are supervised non-specialists who have some interest or experience in mental health care and are trained for approximately 5 days in counselling skills, risk management (how to deal with suicidality or protection concerns) and in the intervention itself. Step-by-step follows the story of a person who is having mood difficulties and accesses treatment. The user can follow the story and apply the skills and lessons to their own life through interactive exercises at the end of each session.

Importantly, in conceptualising Step-by-Step, a number of considerations were made from the outset in order to design a truly global product to be as inclusive as possible in terms of equity of access and relevance, and which could scale up in low-resource areas. The intervention would have to be as culture-fair as possible, in order to facilitate adaptation ahead of use in diverse settings. The brief for the Step-by-Step story was for simple and clear language, so that people with primary school-level education would be able to engage and so that it can be easily translated into other languages. It would need to be vague enough for it to be adaptable and work across a number of contexts and settings, but also evoke enough emotion that it would motivate users to engage with and continue the programme. For example, it was imperative that any software necessary for running the intervention was open access and that the programmer would write a manual for its use and maintenance that could be easily translated. A guide concerning data protection and privacy for countries who may not have any legislation or policy guidance of their own would also be important as part of the Step-by-Step package. The intervention would have to be as light as possible in terms

of the data needed to run it in order to enable usage in low bandwidth areas. The intervention should have on and offline capabilities (so there is not a need for constant internet connection). Voice-overs or videos could engage people with low literacy levels or a preference not to read a story. For Lebanon, a country with many different religious groups, being able to choose the main character was very important, e.g., a bearded male and an un-bearded male or a veiled or unveiled female character. More information on step-by-Step and its design considerations can be found in chapter 5.

Need for cultural and contextual adaptation

The debate around mental illness and cultural equivalence in psychiatry is well established. An evolution of social and medical anthropological perspectives on mental health can be seen, from the now seemingly outrageous and racist theories[3], to today's conception that mental suffering is universal yet nuanced by culture (through its effects on social determinants of mental health and health beliefs and behaviours) (58). Historically, mental health nosology and measurement, as well as care and treatment approaches, have been developed in North America, Australia and Europe and exported directly to other contexts and cultures (59). The validity and universality of these conceptual models and approaches is complex. While the world over, there are similarities in presentations of depression-like states for example, sleep problems, lack of energy and low mood, there exist many accounts of localised idioms of distress and explanatory models of mental illness (58,60). One recent systematic review by Haroz et al (60) illustrated that depression-like syndromes, particularly in non-Western settings and cultures, constitute some symptoms that do not feature in the diagnostic criteria of the main current classification system for mental illness (the Diagnostic and Statistical Manual 5th edition, DSM-V). These include loneliness, thinking too much, headaches and a weak/heavy/painful heart.

Out of respect and a moral obligation to ensure that local mental illness models, values and treatment goals are incorporated into person-centred care wherever the patient is presenting, local adaptation of both measurement and treatment is necessary. What constitutes a positive outcome to treatment of distress is very likely to be personal to the beneficiary and could be discordant with nomothetic (universalistic) measurement instruments (59). Mental health and illness is many-faceted, and measures using only Western-derived symptom severity may overemphasise clinical changes and omit insight into social gains or wellbeing (59). Part of this thesis argues the importance of including aspects of functioning and, if possible, patient generated ideas as to wellbeing in cross-cultural mental health research (See chapter 3).

A patient generated outcome measure (PGOM) is a measure where one or more items are stipulated by the respondent. This means that the measure can provide insights into local treatment goals, problems and priorities, and by definition provides a person-centred approach to measurement. In bringing to light locally perceived problems and their magnitude, service users feel listened to and delivery of care can be slightly tailored.

Evidence-based psychological interventions are making their way to diverse contexts and cultures and to resource-strained settings(28). This global reach of therapy and its effectiveness research

[3] e.g., a WHO publication arguing that depression among Africans was mainly due to malnutrition and that they didn't have the cognitive or cultural capability to be depressed, circa 1953 (57).

highlights a need not only for measurement to be person-centred, but for tools to be translated and adapted for the intervention and its delivery to be culturally and contextually targeted. Theoretically, an intervention that lacks relevance to its user will be less effective than one that is in line with user's needs, values and preferences (61). Evidence for this claim is contradictory. Some meta-analytic evidence shows that face to face psychological interventions that have been adapted are effective (62) and furthermore that their effectiveness increases as the extent of adaptation increases (63–65). A systematic review of middle-Eastern studies (with narrative analysis of studies included) showed that a major barrier to the success of psychological interventions was cultural incompatibility (66). While meta-analyses exist on the topic of adapted interventions, there is a lack of trials that directly compare adapted interventions with non-adapted ones (65,67). One meta-analysis including analysis of adapted versus unadapted interventions showed a small effect size of d=0.32 in favour of adapted interventions, however the included studies had N of 13 to no more than 110 (63). Conversely, one large meta-analysis did not show superiority of adapted interventions to other non-adapted ones (28), though did state that it was difficult to ascertain adaptation status with such short intervention and adaptation descriptions in published papers, also echoed in other reviews (62,67). Compounding the complexity in the debate is that other factors have been found to influence the efficacy of an adapted intervention, such as age, language and ethnic homogeneity of group members in group interventions and language match (to the facilitator) (67). Additionally, the mechanism behind higher effect sizes in adapted interventions is open to interpretation, e.g., it may be that adaptation improves acceptability and completion rates rather than improving the effectiveness of the intervention itself.

Given the need for and the rise of scalable interventions with innovative delivery methods such as self-help or internet delivery, this PhD research also explores the relationship between extent of adaptation and effectiveness of self-help interventions (see chapter 4). Adaptation of these interventions could be even more important, due to the lack of a therapist to reduce cultural disparity and assist the cultural dimension through discussion.

Translation and adaptation should be systematic and community driven by working with potential users of the intervention (61,68). The extent of adaptation should be monitored so as to ensure that the resulting intervention preserves the therapeutic content and spirit of the original intervention, so avoiding a "fidelity-adaptation dilemma" (68). This dilemma once again arises from a contest between a nomothetic and top-down approach of closely adhering to a (normally Western conceived) intervention and an idiographic, and bottom-up and more person-centred approach, respecting and embracing cultural difference through adaptation (61,68). If no efforts are made to adapt, the result may be more true to the intervention that was proved effective in its original target group, however, it may be less suited to the target user and result in adherence issues if deemed unacceptable by culturally diverse users. This is not to say that adaptation and fidelity are dichotomous. Having experts in both the local culture (preferably end users of the intervention) and in psychological theory and practice involved in adaptation should ensure an acceptable and tailored compromise which remains, at its core, the original evidence-based intervention.

The fidelity-adaptation dilemma is perhaps even more pronounced when we consider scalable interventions. Recall that scalable interventions are designed to be delivered by non-specialists or are self-help/minimally guided. A non-specialist facilitator is expected to adhere very closely to an intervention manual, because they do not have the formal training and extensive experience that a

psychologist has. A psychologist will be more able to deliver therapy in a more eclectic or ad hoc fashion, adapting the manual to the client as they go. With self-help materials, there is no therapist to buffer any cultural discordance between the intervention and the client, again rendering adaptation even more important than with traditional, face-to-face therapies.

There are a number of frameworks used to discuss adaptation in the literature on cultural adaptation of psychological interventions, many of which were conceived in the context of providing therapy to culturally diverse groups in the United States of America. Table 2 provides an overview of five such frameworks, ranging from simple two dimensional models, to nine dimensional models. There is overlap between some of the frameworks, e.g., most acknowledge the context of the target community, the ethnicity and cultural identity of the facilitator and client, local beliefs and practices and the client's goals for therapy.

Table 2. Overview of some conceptual frameworks for cultural adaptation of psychological interventions.

Author	**Dimensions**	**Examples of dimensions**
Reniscow et al, 2000 (69)	**2 dimensions:** Surface and deep structure adaptations	Surface adaptations are superficial details in the intervention, such as character names, reference to foods, clothing, and ethnicity in visual materials that can help the beneficiary relate to and engage with the intervention. Deep structure adaptations are more likely to have direct impact on therapeutic change and include values, belief systems and socio-cultural norms.
Bernal and Santiago 1995 (70,71)	Ecological Validity Model (EVM) **8 dimensions:** language, persons, metaphors, content, concepts, goals, methods, and context	Language can be the mother tongue of the facilitator and language that materials are written in but also elements of translation like sayings and colloquialisms; Persons is the cultural match or mismatch between the facilitator and the client; Metaphors are figures of speech or sayings which are not literal but carry a specific meaning to a culture or linguistic group; Content includes the stories, examples and other subject matter; Concepts include the ideas and notions of the intervention; Goals includes how local values affect treatment goals of the beneficiaries; the Methods include delivery format, mechanisms and techniques for therapeutic change; Context is for example local security, socio-political characteristics and norms that may affect the intervention and how to improve feasibility.
Dengan et al 2018 (65)	Themes derived from analysis of adapted	Some overlap with the ecological validity model dimensions, such as treatment goals, but additional dimensions include Family, being the family processes

	studies retrieved in a systematic review **9 dimensions:** Language, concepts, family, communication, content, cultural norms and practices, context and delivery, therapeutic alliance, and treatment goals	and role of the family in recovery; communication includes culturally appropriate ways of dealing with conflict or learning techniques; Norms and practices include religious or spiritual practices or culture-specific coping mechanisms; Therapeutic alliance is similar to persons in the EVM, but also could incorporate trust-building exercises, certain interpersonal rituals like drinking tea together or small talk.
Castro et al 2004 (68)	**3 dimensions:** Cognitive, Affective-motivational and Environmental	Cognitive includes language, teaching strategies, information processing characteristics (comprehensibility and cultural relevance); Affective-motivational relates to what extent content is in line with norms and values; Environmental includes characteristics of the local community and context and the ease of integration of intervention concepts into daily life.
Hwang 2006 (72,73)	Psychotherapy Adaptation and Modification Framework **6 dimensions:** Dynamic issues and cultural complexities; Orientation of clients to therapy; Cultural beliefs; Client-therapist relationship; Expression and communication; and other cultural issues of salience.	Dynamic issues and cultural complexities relates to incorporating understanding of potential cultural moderators; orienting clients to psychotherapy includes increasing mental health awareness, aligning therapeutic goals and managing expectations; Cultural beliefs about distress and treatment; Expression and communication styles particularly regarding distress ; Other cultural issues could include population-specific elements like migration or acculturative stress.

It seems that the aim of these frameworks is to create a common language for discussing cultural adaptation and to pave the way for adaptation procedures, i.e. ensuring that every dimension is covered in adaptation research.

The translation and adaptation of intervention materials including consent forms and training manuals can be an ongoing process. Documents often develop and change over the duration of a project, through translation, testing, training of intervention providers, and after pilot use with the

target community. This thesis includes qualitative methods of cultural adaptation of Step-by-Step for two diverse populations using focus groups and interviews (see chapter 4).

Formative work before running RCTs

WHO has an internal policy that each scalable psychological intervention must be shown to be effective in two fully-powered randomised controlled trials in diverse settings before it can be positively recommended for implementation. This is in line with other international and national regulatory agencies, including the European Medicine Agency and the US Food and Drugs Administration. In addition, WHO follows the United Kingdom Medical Research Council (MRC) approach and guidance on developing, piloting and feasibility testing, evaluating, reporting and implementation of complex interventions in health (74). A "complex intervention", which is one with several interacting components, necessary behaviours and actors, should have a clear theoretical basis, be evidence-based and be replicable for research and implementation. Through piloting and feasibility testing, intervention designers and researchers should be able to estimate whether the intervention is safe and likely to be effective and to better design the research for formally evaluating the intervention, e.g., the recruitment methods, retention rates, outcome measures, length of follow-up and implementation method (74). Researchers can then be clear about the design of the evaluation, including power calculations, randomisation and recruitment techniques. Psychological research can get particularly complicated because of design considerations such as clinical supervision of implementation providers, fidelity checking and active control conditions. The guidance proposes reporting results of such evaluation in terms that service managers and decision makers can understand and that aiding implementation should be considered from the outset, including having stakeholder involvement throughout the process.

The MRC approach has been instrumental in developing and testing WHO scalable interventions. Interventions are designed for low-resource settings with sometimes complex considerations such as active conflict or refugee camps and are intended for eventual scale-up in a range of health care settings and countries. Considerations that the WHO team has met in feasibility testing have ranged from preventing contamination across randomised groups by cluster randomisation at village level; flooding in Kenya preventing recruitment and assessment; security concerns in Taliban-occupied areas in Pakistan; and risk of gender-based violence in Lebanon as a result of study staff contacting participants using shared phones. Part of this thesis reports on the feasibility testing of Step-by-Step and the research design considerations that emerged as a result (see appendix 4).

Aim of the work contributing to this thesis

The aim of this thesis is to share the complex considerations and experience of designing and adapting a scalable intervention for testing in Lebanon. Lebanon is a middle income country with high need for evidence based mental health care and a very high treatment gap. It is a culturally diverse country with a complex history of colonisation and conflict and a pressured and under-funded mental health system, making this experience an interesting and engaging case study. More details about the context and the intervention can be found in subsequent chapters of this thesis. The objectives of the work as part of this PhD between 2015 and 2018 were four-fold:

- To design a WHO e-mental health intervention to be used globally
- To illustrate the need for contextual adaptation of evidence-based interventions and their evaluation methods
- To work with WHO and local actors for the cultural and contextual adaptation of the Step-by-Step intervention, and its pilot testing and scale-up in Lebanon
- To carry out a feasibility study to inform research methods in subsequent project phases that will formally assess the efficacy of Step-by-Step in Lebanon

Research questions

- Do qualitative responses collected as part of a person generated outcome measure bring added value to mental health research in diverse contexts?
- Does cultural and contextual adaptation of self-help interventions have an effect on their efficacy?
- What are the necessary design considerations when conceptualising a minimally guided e-mental health intervention (Step-by-Step) for global usage?
- What are the necessary cultural and contextual adaptations when using Step-by-Step in two diverse settings, Lebanon and Macau?
- Is Step-by-Step accepted and feasible for the treatment of common mental disorders in Lebanon?
- What are important research design and intervention delivery considerations ahead of further testing of Step-by-Step in Lebanon?

Chapter 3

Person Generated Outcome Measurement in Pakistan and Kenya

Harper Shehadeh M., van't Hof E., Schafer A., van Ommeren M., Farooq S., Hamdani S.U., Koyiet P., Akhtar P., Masood A., Nazir H., Dawson K., Albanese E. (2019). Using a person generated mental health outcome measure in large clinical trials in Kenya and Pakistan: Self-perceived problem responses in diverse communities. Transcultural Psychiatry. 57, (1):108-123

Using a person-generated mental health outcome measure in large clinical trials in Kenya and Pakistan: Self-perceived problem responses in diverse communities

Abstract

Health care should be informed by the physical, socioeconomic, mental, and emotional well-being of the person, and account for social circumstances and culture. Patient generated outcome measures can contribute positively to mental health research in culturally diverse populations. In this study, we analysed qualitative responses to the Psychological Outcome Profiles (PSYCHLOPS) Questionnaire—a patient-generated outcome measure based on open-ended questions, and compared the qualitative responses gathered to conventional, nomothetic measures used alongside the PSYCHLOPS in two studies. Data were collected as part of outcome research on a psychological intervention in Pakistan (N = 346) and Kenya (N = 521). Two researchers coded the qualitative responses to the PSYCHLOPS and identified overarching themes. We compared the overarching themes identified to the items in the conventional, nomothetic outcome measures to investigate conceptual equivalence. Using the PSYCHLOPS, the most frequently reported problems in Kenya were financial constraints, poor health, and unemployment. In Pakistan, the most frequent problems were poor health and emotional problems. Most of the person-generated problem concepts were covered also in nomothetic measures that were part of the same study. However, there was no item equivalence in the nomothetic measures for the most frequent PSYCHLOPS problem cited in both countries. Response bias and measurement bias may not be excluded. More research on the use of PSYCHLOPS alongside conventional outcome measures is needed to further explore the extent to which it may bring added value. Use of a PSYCHLOPS semi-structured interview schedule and efforts to minimise response biases should be considered.

Introduction

According to the World Health Organization's (WHO) global strategy on people centred and integrated health services (WHO, 2015), person-centred care should focus on the health needs, preferences, and expectations of people, rather than being disease-focused. In particular, this WHO strategy suggests that care should be centred on the physical, socioeconomic, mental, and emotional well-being of the beneficiary, and should account for people's social circumstances and culture. Consideration of culture and individual experience is at the core of person-centred medicine (Mezzich, Botbol, & Salloum, 2016). In line with the person-centred approach are ''emic'' or idiographic approaches to measurement that favour individuals' perspectives, uniqueness, and the contextualisation of observed phenomena (Alegria et al., 2004; Berry, 1969). However, outcome studies in mental health tend to use ''etic'' or nomothetic outcome measures, which favour objectivity and comparability across settings and populations.

Person-centred approaches to measurement may be particularly important in international or cross-cultural mental health research, where the debate on measurement validity across cultures is still ongoing (Betancourt et al., 2009; Kirmayer & Pedersen, 2014). Mental health care and research in

many countries are largely dominated by models, methods, and measures that are generalised and etic and that tend to have been developed in high-income countries. The extent to which these models and methods have been adapted for use in diverse settings and cultures varies, but engaging with people's experience by using person-centred measures could ensure that local values, perspectives, priorities, and expectations are not overlooked (Kirmayer, Mezzich, & van Staden, 2016; Kirmayer & Pedersen, 2014), and could potentially form the basis of measured change.

Patient-generated outcome measures (PGOMs) are idiographic and defined as measures where the items are determined by the help-seeker (Ashworth et al.,2004). PGOMs are therefore person-centred and emic by definition. PGOMs are designed to capture the individual's personal illness experience and to account for this experience, while testing the efficacy or effectiveness of treatments and interventions. Researchers in the field of person-centred care and outcome assessment are calling for a mixture of nomothetic (general) and idiographic (e.g., PGOMs) measures to be used as standard practice in mental health research (Green, 2016; Pesola et al., 2015; Rose, Evans, Sweeney, & Wykes, 2011; Sales & Alves, 2012). This hybrid approach acknowledges the weaknesses and strengths of both approaches, and could potentially contribute to strengthen mental health research conducted across and within cultures and settings. PGOMs may contribute to the integration of emic and etic approaches in mental health research. Hence, it is important to investigate the acceptability, feasibility, and added value of using PGOMs in diverse settings.

One example of a PGOM is the Psychological Outcome Profiles Questionnaire (PSYCHLOPS). It was originally developed as both a therapeutic tool and as an outcome measure to assess the effectiveness of psychological interventions delivered in primary care settings in the United Kingdom (UK). The tool can also be used as a gateway to therapeutic discussion, for baseline assessment, and for monitoring progress (Ashworth et al., 2004). The PSYCHLOPS is truly emic in that it has a qualitative component, whereby it asks respondents about their problems or functioning limitations. Each qualitative question is followed by a quantitative, Likert scale question to rate the impact and duration of the problems or limitations elicited.

Three previous studies, all from the UK, have explored the qualitative results of the PSYCHLOPS questionnaire (Ashworth et al., 2007; Lawton et al., 2014; Robinson, Ashworth, Shepherd, & Evans, 2007). Coding of responses differed across these studies. Robinson et al. (2007) coded the qualitative responses into seven main themes (interpersonal, state of mind, somatic, past events, competence/ performance, self-evaluation, and material issues), and two to four subthemes (17 in total). The same seven high-level problem themes were used in a subsequent publication, though were further defined into 61 subthemes for both the problem and the functioning domains of the PSYCHLOPS (Ashworth et al., 2007). Lawton et al. (2014) coded three problem and functioning themes (physical, psychological, and social), further stratified into nine subthemes (e.g., social work, social money). Evidence from one of these studies (Ashworth et al., 2007) suggests that the PSYCHLOPS reported problems may be more comprehensive than those captured using a quantitative, fully structured nomothetic instrument. When the authors compared the PSYCHLOPS reported problems to the content of the Clinical Outcomes in Routine Evaluation-Outcome Measure (CORE-OM; Evans et al., 2000), they found that several person-generated problems did not feature in the nomothetic questionnaire (Ashworth et al., 2007).

WHO obtained permission to incorporate the PSYCHLOPS into the manual of one of their scalable psychological interventions, Problem Management Plus (PM+; Dawson et al., 2015; WHO, 2016).

PSYCHLOPS' focus on the person's problems means that the questionnaire lends itself to the problem- solving elements of the intervention, is simple to use, and aids therapeutic dialogue. Moreover, the emphasis on the individual's perspective was intended to capture concerns of greatest personal significance, which are deemed particularly important in people affected by adversity, rather than relying solely on an external frame of reference to interpret psychological distress and recovery. PSYCHLOPS was used as an outcome measure in two large randomised controlled trials (RCTs) designed to test the effectiveness of PM + in reducing symptoms of common mental disorders in Pakistan and Kenya.

In this article, we analyse qualitative responses to the PSYCHLOPS questions and compare these responses to the conventional, nomothetic measures used alongside the PSYCHLOPS in the two research trials.

Methods

Setting

Data were collected as part of two RCTs conducted in Pakistan and Kenya, which have been previously described (Bryant et al., 2017; Rahman, Hamdani, et al., 2016; Sijbrandij et al., 2016; Sijbrandij et al., 2015). Briefly, the RCTs tested the individual version of PM+, a brief (five-session) individual psychological intervention that was delivered by closely supervised non-specialists (Dawson et al., 2015; WHO, 2016). PM + was developed because it is potentially scalable in resource-pressured health systems and because its components are evidence-based, using a multicomponent approach with elements of problem-solving combined with behavioural techniques. PM + is transdiagnostic in that it addresses symptoms of diverse mental health problems (e.g., depression, anxiety) as opposed to symptoms of single diagnoses, and it was designed specifically for people living in communities affected by adversity and/or for resource-pressured health systems. Between 2014 and 2016, PM + was tested among adults with psychological distress in peri-urban Peshawar, Pakistan, and in suburban Nairobi, Kenya. Both trials indicated PM + to be effective at reducing symptoms of psychological distress, including depression and anxiety symptoms, and at improving one's degree of functioning (Bryant et al., 2017; Rahman, Hamdani, et al., 2016).

The PSYCHLOPS measure

PSYCHLOPS consists of three domains and four questions: problem domain (two questions), function domain (one question), and well-being domain (one question). It is designed to be administered before, during, and after an intervention. The versions for the different time points differ slightly. In the pre-intervention version, participants are first asked to think of their problems, to choose two problems that trouble them most, and to indicate on a 6-point Likert scale (0 = not at all affected, 5 = severely affected) how much the problem has affected them in the last week. This is followed by a question on functioning that is thereafter also rated on a Likert scale. In the during- and post-intervention PSYCHLOPS versions, people are asked to think of the same problems that were previously mentioned in the pre-intervention version and to indicate again how much they have affected them in the last week. There are other questions in the PSYCHLOPS that do not contribute to the scoring, such as questions on temporality of problems in the pre-intervention version, a question on a new problem and its magnitude in the during- and post-intervention versions, and a comparison of how the person feels since starting the intervention in the post-intervention version.

PSYCHLOPS has been validated in primary care populations in the UK, Iceland and Poland (Ashworth, Evans & Clement, 2008; Ashworth et al. 2005; Czachowski, Seed, Schofield, & Ashworth, 2011; Hedinsson, Kristjansdottir, Olason, & Sigursson, 2013), but never outside of Europe.

Adaptation of the PSYCHLOPS

In both sites, the PSYCHLOPS questionnaire was used as an interview measure, not as a self-report measure as it was designed, allowing for inclusion of illiterate respondents. For maximum brevity, two items that do not contribute to scoring were removed from the pre-intervention version of PSYCHLOPS. These were Item 1c (''How long ago were you first concerned about this problem?'') and Item 2c (''How long ago were you first concerned about this problem?''). Also, in Pakistan only, Questions 5a and 5b concerning other important problems since therapy began, were removed from the during-intervention version, and Questions 5 and 6 regarding other problems since therapy began and the way patients felt compared to when they started therapy, were removed from the post-intervention version of the PSYCHLOPS. While these questions were kept in the Kenya study, they had a very low response rate, and were not included in analyses of this current study. None of the removed items mentioned above contributed to the PSYCHLOPS overall score. See supplemental material for the modified pre-intervention PSYCHLOPS used in Pakistan.

The questionnaire was translated into Swahili (by a language specialist) and Urdu (by a member of the team), and was reviewed by bilingual mental health experts (Pakistan) or community health volunteers (Kenya). The process in both sites included blind back-translation to ensure integrity of the translation. The teams found that the simplicity of the PSYCHLOPS and its non-diagnostic, non-stigmatising language lent itself to ease of translation. There was just one slight language revision to the Urdu version only: ''[How have you] felt in yourself [this last week?]'' was translated as ''aapna kaisaameh sooskia,'' which is a simpler formulation, meaning ''How did you feel this week?'' After feedback during the pilot, this was considered a more culturally appropriate and everyday way of asking about one's feelings and sense of well-being. All measures and intervention materials were also tested in pilot trials (Dawson et al., 2016; Rahman, Riaz, et al., 2016).

Procedure: Data collection

The details of the data collection procedure used in Pakistan and Kenya are provided elsewhere (Bryant et al., 2017; Rahman, Hamdani, et al., 2016; Sijbrandij et al., 2016; Sijbrandij et al., 2015). In summary, in Kenya, female adult participants were recruited by systematic random sampling (every 10th home in a given catchment area) and, upon receiving informed consent, a maximum of one woman per household was screened for inclusion in the trial by an independent assessor. In Pakistan, male and female primary care clinic attendees were informed about the study, and those who provided informed consent were screened for trial inclusion by a trained research assistant. Subsequent assessments were completed by an independent assessment team.

In both sites, the PSYCHLOPS was included as a secondary outcome measure at pre-, post-, and 3 months follow-up in both PM + treatment and control conditions. It was also used at the beginning of each of the five PM + sessions to aid elicitation of the problem(s) that were perceived to be causing concern or troubles, and was used in Kenya as an inlet to clinical supervision, as the PSYCHLOPS is part of the PM + protocol (WHO, 2016).

Participant screening, interventions, and assessments took place in participants' homes in Kenya between April 2015 and January 2016, and in the primary health clinics (PHCs) in Pakistan between November 2014 and January 2016. Participants who scored a minimum of 3 on the 12-item General Health Questionnaire (GHQ-12; Goldberg & Williams, 1988) and 17 on the WHO Disability Assessment Scale (WHODAS; Ustun, Kostanjesek, Chatterji, Rehm, & World Health Organization, 2010), in both Kenya and Pakistan, were invited to the trial. In both sites, participants were excluded if they were under 18 years old, screened as being at imminent risk of suicide, or judged by the trained assessors as having severe mental disorder or cognitive impairment (e.g., psychotic disorders, substance use disorder).

Depending on the phase of the research (e.g., pre- and post-assessment or during the intervention), the PSYCHLOPS questions were asked by trained assessors or the PM + provider. The interviewer then documented responses in the assessment pack, having been instructed to cite the problems as per the participants' response. In the during- and post-intervention versions of the PSYCHLOPS, Questions 1–3 ask the participant to reflect on the qualitative answers cited in the pre-intervention version. The PM+ providers in Pakistan did not ask these open-ended questions a second time, whereas in Kenya they did re-ask the questions.

Data entry was carried out in Pakistan by a bilingual member of the research team who translated exactly what was recorded in the assessment pack directly into Stata Version 11.2. Another bilingual team member then checked the translations. In Kenya, Swahili was translated into English verbally by a bilingual team member and entered into SPSS by the English-speaking data-entry person. It was not checked again. In both study sites, quantitative data were double-checked to ascertain accuracy of data entry.

Data coding

Categorisations for PSYCHLOPS have been used previously in three studies from the UK (Ashworth et al., 2007; Lawton et al., 2014; Robinson et al., 2007), but due to the geographical and cultural diversity of the populations under study, researchers used a data-driven approach. Two researchers (MHS and EvH) independently coded the responses given to the qualitative items of PSYCHLOPS to identify themes in a two-step process. Firstly, they each coded the responses and compared their sets of themes. They removed duplicate themes, condensed similar themes, and obtained the final list of themes and their respective codes through discussion. Using this final list of agreed themes and codes, the researchers recoded the data for each country separately. To retain the granularity of responses, two levels of coding were assigned. For example, ''financial constraints'' would receive a numeric code and, if a participant was specific about the financial problem (e.g., ''Can't pay school fees''), the problem was coded as a numeric plus a letter code (e.g., 3c).

A problem or limitation would receive its own code provided that its frequency was more than 10 mentions across the sample or, for the Kenya sample, if a problem was seldom cited but related to gender-based violence (GBV; because this was a focus of the Kenyan study). In both cohorts, in the event of participants citing a further problem, or an answer not including a verb in response to the functioning limitation Question Q3a, ''Choose one thing that is hard to do because of your problem (or problems),'' the ''Did not cite an activity'' code category was assigned. The ''Other'' code would be used in instances where the meaning of the response was not clear or when an existing code was not suitable.

In cases where more than one problem was cited, coders had originally planned to code only the first response, in line with established PSYCHLOPS coding techniques (Ashworth et al., 2007; Lawton et al., 2014; Robinson et al., 2007). However, in Pakistan, multiple problems were very often cited. In order to be able to consider the problems deemed most important to respondents in Pakistan, coders retained the first three problems in response to Question 1a: ''Choose the problem that troubles you most.'' Conversely, in Kenya, multiple responses to questions were less frequent, so only one problem was coded by the researchers for each question.

Data analysis

We described the sociodemographic characteristics of the two samples. Given that each data string was short (approximately two to 30 words), we used Microsoft Excel to manage the coding process. Coding discrepancies were resolved by discussion between MHS and EvH. We conducted inter-coder reliability checks and calculated the percentage of agreement in coding. We compared the themes to the items in the nomothetic outcome measures to investigate conceptual equivalence between PSYCHLOPS and other nomothetic measures. The nomothetic measures used across the two studies were the WHO Disability Assessment Scale (WHODAS; Ustun et al., 2010); the General Health Questionnaire-12 (GHQ-12; Goldberg & Williams, 1988); the nine-item version of the Patient Health Questionnaire (PHQ-9; Kroenke, Spitzer, & Williams, 2001); the PTSD Checklist for DSM-5 (PCL-5; Weathers et al., 2013); the Hospital Anxiety and Depression Scale (HADS; Mumford, Tareen, Bajwa, Bhatti, & Karim, 1991); the Life Events Checklist (Gray, Litz, Hsu, & Lombardo, 2004); the Pakistan Life Events Checklist (LEC-P; Gray et al., 2004; Husain et al., 2011); and the WHO Violence Against Women (WHOVAW; Garcıa-Moreno, Jansen, Ellsberg, Heise, & Watts, 2005)

Results

Characteristics of participants

Across the two study sites, a total of 867 participants completed the pre-intervention PSYCHLOPS questionnaire (521 from Kenya and 346 from Pakistan). Table 1 shows the sociodemographic characteristics of the two populations. As Table 1 shows, the Kenyan population was, on average, 3 years older, considerably more educated than the Pakistani population, was less functionally impaired, and scored lower for mental health problems than the Pakistani population, as measured by the WHODAS and the GHQ. Much more of the Kenyan population was employed or self-employed compared to the population in Pakistan, who were more commonly homemakers. Divorce or separation was rare in Pakistan.

Table 1. Demographic characteristics of the two populations

Variable	Kenya	Pakistan
Total number of participants	521	346
Mean age, years	36	33
Age range, years	18-89	18-65
Mean pre-PM+WHODAS score	27.6	34.4
Mean pre PM+ GHQ-12 raw score	18.9	25.5
	Frequency (%)	Frequency (%)
Gender		
Female (%)	521 (100)	273 (78.9)
Education		
Uneducated	35 (6.7)	203 (58.7)

Completed primary school (8 years)*	288 (55.3)	68 (19.7)
Marital status		
Married/cohabiting	288 (55.3)	221 (63.9)
Divorced/separated	104 (20.0)	7 (2.2)
Never married	76 (14.6)	101 (29.2)
Widowed	49 (9.4)	17(4.9)
Employment status		
Unemployed	47 (9.0)	18 (5.5)
Retired	3 (0.6)	3 (0.9)
Homemaker	200 (38.4)	231 (66.8)
Paid employment	131 (25.1)	41 (11.8)
Self-employed	124 (23.8)	26 (7.5)
Other	12 (2.3)	26 (7.5)

Note. PM+ = Problem Management Plus; WHODAS = World Health Organization Disability Assessment Scale; GHQ = General Health Questionnaire. *The education data on past primary school became non-comparable due to the manner in which the question was posed to participants at the two study sites

The following section will present the results for the two PSYCHLOPS questions on problems (primary problem and another problem) for Kenya and Pakistan, followed by the functioning question results.

Qualitative results from PSYCHLOPS: Problem domain

Table 2 provides the frequencies of high-level codes assigned to the first response given in both Pakistan and Kenya to Questions 1a (primary problem) and 2a (other problem). Most high-level codes were present in the two countries, such as poor health, financial problems, and emotional problems, but with different frequencies.

Table 2. Frequency of first responses to PSYCHLOPS primary problem question(1a) and other problem question (2a)

Frequent problem code	Primary problem, % (n)		Other problem percentage, % (n)	
	Kenya (n=521)	Pakistan (n=346)	Kenya (n=346)	Pakistan (n=345)
Unemployment	12.1 (63)	Not coded	6.7 (25)	Not coded
Poor health	25.4 (132)	66.8 (231)	29.1 (108)	13 (45)
Financial problems	40.8 (212)	1.7 (6)	29.6 (110)	9 (31)
Psychological/emotional	4.8 (25)	25.1 (87)	8.4 (31)	37 (128)
Interpersonal problems	7.7 (40)	1.7 (6)	8.9 (33)	19.4 (67)
Other person's health problems	2.5 (13)	Not coded	4.3 (16)	Not coded
Other	6.7 (35)	4.6 (16)	9.4 (35)	20.5 (71)
No second problem cited	Not coded	Not coded	3.5 (13)	1(3)

Table 3: Examples of responses to PSYCHLOPS questions on problem domains from both countries

Kenya example responses	Pakistan example responses
Question 1a: Choose the problem that troubles you most.	
Desires to start a mitumba business but lacks the financial capital	*Stomach problem, poverty. Husband is employed and kids' problems.*
Lack of peace in the house due to her husband	*Poverty. My son is ill and there is a problem in his treatment so we are worried*
Getting food for the orphans she has	*Dizziness, gets angry, beats my children, gets worry*
Money to start a business, buying a plot and for educating her children	*Severe headache, feels sad*
Unemployment hence no money	*Headache bothers me a lot. Stomach problem*
Stressed over the disobedient son. Stress	*Headache, I feel burdened and angry.*
She is diabetic, screams at night, insomnia	*Headache, feel burdened, spells of unconsciousness*
Financial constraints	*Headache, dizziness, feeling sick to the stomach/nausea*
Living situation is dire	*I feel burdened, sleep issues, I feel sad, feel like staying alone these days.*
Body pains	*Headache. I feel burdened. Sleep issues. Fear and suffocation.*
Question 2a: Choose another problem that troubles you.	
Isolated by the family	*I get bothered due to family problems. I don't feel interest in any work*
Lack of proper housing	*Loss of interest in activities and laziness*
Taking care of all responsibilities	*I feel angry and fearful*
Ulcers	*Fear, get angry, weak memory.*
Paying school fees for her children	*Don't have good relations with husband. I feel angry.*
Money for rent and buying food	*Short temper, diet/nutrition problem*
Sickling child. The last born kid has diarrhoea	*Body-aches. I feel sad, headache, sleep disturbances*
Difficult in providing for her mother back at home	*I feel like crying. Home issues. Lack of self-confidence. Want to study engineering. I don't have good relations with siblings*
Money for upkeep, she gets paid late	*I feel sad. Thinks about my future. I am worried for my children. fights with husband*
Less revenue from the business	*Disappointment. I feel sad.*

Kenya. Table 2 shows that in Kenya, the most frequent primary problem mentioned was financial problems (40.8%) followed by poor health (25.4%) and unemployment (12.1%). The most frequent responses for the other problem question were financial problems (29.6%) and poor health (29.1%). All other categories of problems for the second problem question were significantly and similarly less

frequent (< 9.4%). In the supplemental material can be found the main eight coded problems with their frequencies for both the primary problem and the other problem questions.

Further breakdown of the coding into the constituent sub-codes shows that, of those whose primary problem was financial (n = 212), 75% cited a general lack of money, almost 10% cited a lack of school fees, almost 10% an inability to pay for basic needs (food and rent), with the final 5% citing they had not been able to develop their business (See Table 4). The rates of these types of financial problems were 49%, 15%, 28%, and 7%, respectively (of a total of 110 women), when considering responses to Question 2a on another problem.

Among those whose primary problem was health, 36% entered a general term for illness or poor health, 38% cited a single health problem (e.g., headache), and 16% cited more than one health problem. Ulcers and reproductive health problems were commonly cited, therefore warranting their own codes, with 5% of all health complaints being ulcers and 5% being reproductive health problems.

In Kenya, though 14–30% of responses showed different codes pre- to post PM+, the overarching themes remained: financial, health, and unemployment-related concerns. A large proportion of the changes over time were not in the problem itself, but in the formulation of the problem, leading to a different code being assigned. For example, for Participant OW32304209, her main problem was ‘‘Educating her children,’’ and in the post-assessment, it was formulated as ‘‘Lack of school fees.’’ Also, ‘‘Providing for the family’’ changed to ‘‘Unable to get money for food’’ (Participant KG21707027), or in the case of the functioning response, ‘‘Cannot work properly’’ changed to ‘‘House chores’’ (Participant MG21607038).

Table 4: Break down of the main two problems in Kenya where more specific information was available.

Of the financial problems in Kenya (N=212)	**Of the health problems in Kenya** (N=132)
General lack of money (75%)	Non-specific poor health (36%)
Lack of school fees (10%)	A single health problem (38%)
Inability to pay for basic needs (10%)	Multiple health problems (16%)
Unable to develop business (5%)	Ulcers and reproductive health problems (10%)

Examples of responses for the problem domain questions can be found in Table 3. Also, participants often cited a problem as their primary problem in the pre-PM + assessment (Q1a), but as their ‘‘other problem’’ in the post-PM + assessment (Q2a). This resulted in a change to the code assigned, but the overarching problems for that participant remained the same.

Pakistan. In Pakistan, the interviewers wrote down several problems in response to the problem domain questions. For example, Participant 41 was cited to have said ‘‘Headache, worry, body ache, problems at home’’ and Participant 124 responded ‘‘Headache, gets angry, sleep disturbance. I am worried due to poverty and house rent.’’ It is for this reason that coders coded frequencies of primary problem responses considering both the first response and the first three responses to the question.

Figure 1 shows the frequencies of pre-intervention problem codes mentioned in Pakistan when only looking at (a) the first problem mentioned, and when looking at (b) the first three problems mentioned in response to the primary problem question. Though burden could be considered a psychological or emotional problem, and headache a physical health problem, due to their high frequency, we have distinguished them from their parent categories of health and psychological/ emotional problems.

In Pakistan, the study population, recruited from primary health clinics, generally complained more of problems related to physical and emotional symptoms. When looking at only the first primary problem response, the most frequent problem was headache, which was reported by 57% of participants. Psychological or emotional problems followed, with 12.8% of the participants mentioning these as their first response to this question. ‘‘Burden’’ was the first cited main problem for 11.8% of the participants.

When looking at the first three problems mentioned in response to the question ‘‘Choose the problem that troubles you most,’’ headache (26%) was reported on a par with emotional problems (26%), burden (20%), and other physical health issues (20%).

Figure 1. Frequencies of pre-intervention problem codes mentioned in Pakistan

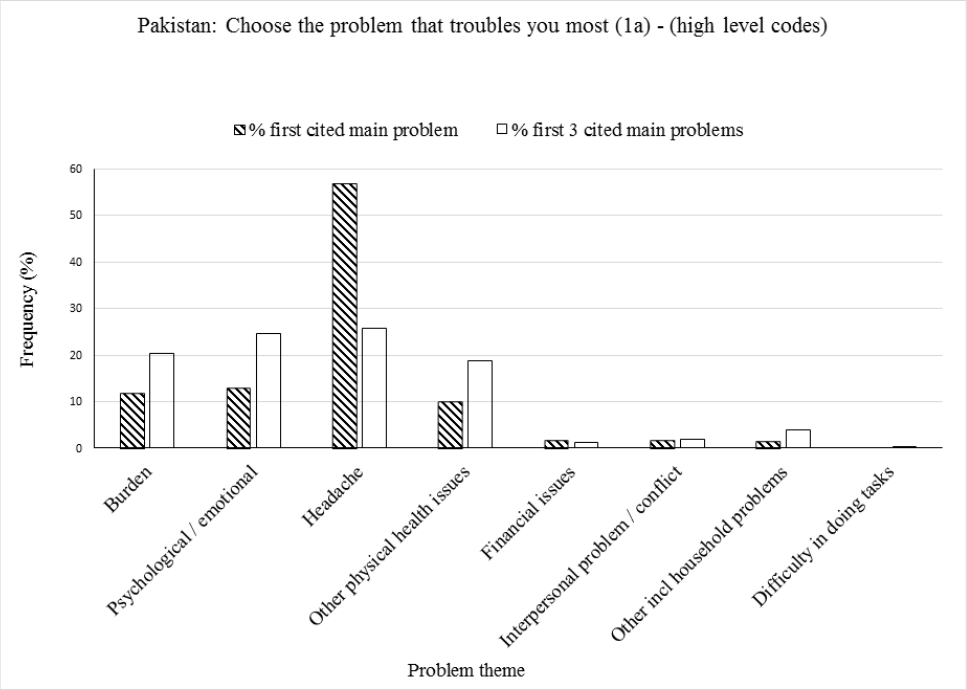

Table 5: Break down of the problems cited within the first three responses to the question 1a in Pakistan

Of the emotional problems in Pakistan	**Of the health problems in Pakistan**
Sad/disappointed (27%)	Headache (56%)
Angry/irritated (27%)	Sleep problems (16%)
Worried (18%)	Other aches and pains (15%)
Fearful (6%)	Non-specific health problems, stomach problems, fainting and dizziness, memory loss, suffocation/breathing difficulties (13%)

Further analysis of the psychological/emotional problems cited in the first three responses to the Question 1a found that, among those whose problems were emotional, 27% said they were sad or disappointed, 27% were angry or irritated, and 18% were worried. The remainder were anxious, fearful, disinterested, or mentioned general emotional issues. Of the physical health problems reported in the first three responses to the Question 1a, headaches made up 56%, other aches and pains made up 15%, and sleep problems accounted for 16% of health problems specified. The rest were cited as nonspecific, fainting and dizziness, or stomach problems.

Though very infrequent (between 1% and 2% of participants each), other problems mentioned in Pakistan included memory problems, suffocation or breathing difficulties, thinking or thinking too much and ‘‘heavy heart.’’

Responses to Question 2a (other problem) are shown in the supplemental material.

Qualitative results from PSYCHLOPS: Functioning domain

Table 6: Examples of responses to PSYCHLOPS questions on the functioning domain from both countries

Kenya	**Pakistan**
Question 3: Choose one thing that is hard to do because of your problem (or problems).	
Lacks interest to look after her husband	*Paying attention to kids*
Can’t pay fees	*Sometimes problems in doing housework*
Can’t draw water	*Worrying thoughts occur. Feels burdened. Can’t do home chores and offer prayer*
Buying drugs and food	*Have difficulty in home tasks/chores*
Can't work well. Home chores	*Can’t do anything. Everything seems difficulty to do.*
Talking to her husband and upbringing of her children	*Problems with work*
Unable to do business	*Don’t socialize*
She can’t be employed because the husband forbids her to leave the house, she had got a job in Dubai	*Worried because of my employment. Because of this I cant do any work.*
Providing for the family	*Home tasks/chores*
Unable to take care of self and of the house	*Can’t talk to anyone. I feel suffocation.*

In Kenya, most women, in response to Question 3a, ‘‘Choose one thing that is hard to do because of your problem (or problems)’’ (referring to problems cited in the previous questions), found it hard to work, run their business, or engage with their educational activities (24%). Almost 16% found it hard to do their chores, 12.5% to pay for things, and 9.6% found it hard to provide for their family (see supplemental material for a visual representation).

Supplemental material includes responses to ‘‘What was the hardest thing to do because of your problem over the last week?’’ in Pakistan. Most reported caring for their family (48.6%) as the hardest thing to do because of their problem. This was followed by working or studying (19.7%) and stating that they cannot do anything (12%). In both study sites, many participants cited a further problem in response to this functioning question (34 participants, or 6.5% in Kenya; 22 participants, or 10.6% in Pakistan).

Only in Kenya did the enumerators report qualitative responses pre- and post-intervention. In the Kenya post-assessment, between 14% and 36% of the qualitative responses to the primary and other problem questions changed pre- to post-PM+. The post-intervention problem codes did not deviate from the overall trend; that is, frequent disclosures of illness, lack of money, and unemployment.

The interrater agreement level for assigned codes for the three qualitative questions was 96%, 94%, and 96% for the Kenya data, and an average of 91.4% for the Pakistan data (considering coding the first three primary problem codes, the first other problem code, and the functioning code). Although this is strong interrater agreement, the slightly higher differences for assigned codes from the Pakistan study were likely due to the greater complexity and multiple problems and/or causes for problems given in the same response.

Comparison to nomothetic outcome measures

Upon comparison of the items in the other questionnaires used to the coded problem themes in the PSYCHLOPS data, most concepts were covered; however, not all of them were. In Kenya, the nomothetic outcome measures used were the WHODAS (Ustun et al., 2010), the GHQ-12 (Goldberg & Williams, 1988), the WHOVAW (Garcıa-Moreno et al., 2005), the LEC-P (Gray et al., 2004), and the PCL-5 (Weathers et al., 2013). Across the conventional measures used in Kenya, there were no items about financial hardship, which was the most frequent problem response in that setting.

The nomothetic outcome measures used in the Pakistan study were the WHODAS (Ustun et al., 2010), the GHQ-12 (Goldberg & Williams, 1988), the PHQ-9 (Kroenke et al., 2001); the PCL-5 (Weathers et al., 2013), the HADS (Mumford et al., 1991), and the LEC-P (Gray et al., 2004; Husain et al., 2011). Though physical health problems are briefly covered in the context of functioning in the WHODAS, there was no item specifically on headache in the Pakistan interview schedule, the most frequent problem response in Pakistan.

The WHODAS has items similar to many of the responses gathered for the PYSCHLOPS functioning question (things the participant finds hard to do) in both Kenya and Pakistan: not being able to carry out household responsibilities and usual responsibilities or work.

Discussion

This study was based on the largest dataset of PSYCHLOPS data ever analysed. Our results show that poor health is perceived as an important issue in both Kenya and in Pakistan. In Kenya, the top three problems cited as a main problem were: lack of money (40.8%, mainly in a general sense, but school fees and basic needs were problematic for many), poor health (25%, mainly with no specific condition mentioned), and unemployment (12%). In Pakistan, the top two main problems were poor health (66.8%, the vast majority being headaches, but also aches and pains, and sleep problems) and emotional issues (25.1%, with almost half cited as ‘‘burden,’’ but also frequent were anger and sadness/disappointment). Other problems in Pakistan accounted for less than 2% of responses each. The functional limitations that participants reported were similar across the two sites, with chores, work, and providing or caring for family being commonly reported as hard to do. Additionally, in Kenya, there were many instances of participants finding it hard to pay for things they needed (12.5%).

Additional feedback from the study team in Kenya found PSYCHLOPS to be an important clinical supervision tool during the PM + facilitator supervision sessions.

Interpretation of results

When considering these results, we acknowledge many social and environmental factors, as well as research design factors and cultural factors that differed between the two sites. One obvious difference is that in Kenya, the sample was comprised of females only, whereas in Pakistan both males and females were recruited (four females for every one male). Also, the sampling method used for recruitment differed across the sites, with the Pakistani study recruiting help-seekers at health centres, and the Kenyan study recruiting in the general community. Poor health was commonly reported in Kenya (almost 30%) but more so in Pakistan (57% headaches and around 10% other health problems). The recruitment strategy could be a reason for more complaints of medical and emotional problems in Pakistan.

In both study sites participants faced remarkable adversity, including high unemployment rates, high levels of poverty, loss, and low educational attainment. Nevertheless, relatively few people in Pakistan and Kenya reported ideas of mental illness, loss, or trauma as one of their main problems. Thus, several social and environmental circumstances, and some features of the study design, were different between the two sites.

Kenya.

In suburban Nairobi, there is a stark lack of attainment of basic needs. One of the study partners, World Vision Kenya (WVK), had been present in the South Dagoretti district for 25 years, supporting children's health, education, food security, and nutrition. In the study areas in Kenya, process evaluation interviews (van't Hof et al., 2018) showed there were expectations among participants that WVK helps families to pay for school fees and buy food. When assessors introduced themselves as working for WVK, such expectations of support from the organisation could have biased the formulation of participants' self-reported problems (despite the informed consent procedure).

Additionally, approximately three quarters of the study population screened for symptoms of common mental disorders disclosed instances of gender-based violence since the age of 15 at pre-assessment (Bryant et al., 2017), yet only six women reported violence as their main or other problem on the PSYCHLOPS. These women's descriptions of their problems did not seem to change thematically after an evidence-based problem management intervention either. Knowledge of the Kenya context suggests the response bias towards financial problems in this population could be sociocultural, where people living in such poverty are more inclined to prioritise and emphasise their basic needs as the primary cause of their problems, and perceive or express other problems such as emotional needs, mental health concerns, or interpersonal violence to be of low importance by comparison. There is also high stigma within the study community around mental health problems, so social desirability and stigma concerns, confidentiality worries, or indeed
low mental health literacy levels among the community may also have contributed to bias.

Prior to implementing the study, the Kenya team undertook a 2-day preliminary ethnographic assessment of mental health concerns in the Nairobi urban context, and whether people perceived mental health concerns as a priority. Findings echoed the PSYCHLOPS results, in that human distress was more likely to be seen as an indicator of the need to address practical life problems (e.g.,

financial constraints) than as a symptom of an emotional or mental disorder requiring treatment. However, when asked how people could recognise individuals experiencing distress, mental, or emotional problems, they mentioned too much alcohol intake, failing to work, or to provide and care for their families. They also commented on signs of low mood, such as social withdrawal, perhaps because of the lack of local language equivalent for words such as depression or anxiety. In addition, there is significant stigma associated with mental illness, and strong beliefs exist in local communities such as mental illness being related to bewitchment, with a need for treatment by traditional healers. Many people from these communities present with physical complaints such as fatigue, headache, or chest pain, rather than with psychological complaints. As such, it seems that, while women in Kenya readily identify individuals in distress, their vernacular around distress tends to be linked to their capacity to meet basic needs and attend to normal daily tasks, rather than to emotional distress.

Pakistan. It is now generally accepted that somatic presentations of psychological distress occur all over the world (Al Busaidi, 2010; Kirmayer, Robbins, & Paris, 1994), and in the primary care setting in Pakistan, studies have shown that the most common presentation of help-seekers with anxiety and depression is with multiple somatic symptoms (Minhas & Nizami, 2006; Mumford, Nazir, Jilani, & Baig, 1996; Mumford, Saeed, Ahmad, Latif, & Mubbashar, 1997). Idioms such as ‘‘this is really giving me a headache’’ are common in many languages to imply that something is causing stress, and common primary headaches have been linked to psychosocial factors (Lebedeva, Kobzeva, Gilev, Kislyak, & Olesen, 2016). Fifty-seven percent of participants in the Pakistan site, who all demonstrated caseness for common mental disorder and functional impairment, reported their main problem as headaches. In addition to aforementioned adversities in the Peshawar community, the respondents were faced with high levels of security threats due to ongoing conflict in the form of the Taliban insurgency. This may have contributed to high levels of psychological distress, which were perhaps manifested in the tendency to experience and express psychological distress in the form of a culturally acceptable (and understandable) somatic symptom.

One explanation offered by the Pakistani team members regarding the expression of distress and communicating problems mainly in somatic terms was the social desirability of expressing distress in terms acceptable to health workers. There is practically no provision for the treatment of psychological distress, especially in primary care, so service users may emphasise a somatic symptom to get the desired attention from the health care providers, meaning that psychological symptoms could remain in the background. Additionally, one fifth of the sample in Pakistan were male. It is an accepted phenomenon that men are less proactive in seeking mental health care than women (Lynch, Long, & Moorhead, 2018), which may also explain that this sample extensively reported somatic symptoms.

Comparison to other PSYCHLOPS studies and to nomothetic instruments

In comparison to two studies of qualitative analysis of PSYCHLOPS responses from the UK (Ashworth et al., 2007; Robinson et al., 2007), both similarities and differences are apparent. In the UK, researchers used main categories, each with sub-categorisations, similar to the coding strategy in this study (albeit organised differently). Many problem categories were similar to those found in Pakistan and Kenya, namely ‘‘interpersonal’’ (including relationships, social interactions, and other’s health); ‘‘state of mind’’ (including diagnostic labels and unhappiness); ‘‘somatic’’ (health concerns and sleep

problems); 'competence/performance'' (including employment); and ''material issues'' (including finances and accommodation). However, primary care and cardiac service users in the UK were also coded as reporting problems with sex, psychiatric diagnostic labels, and past events like loss or trauma (Lawton et al., 2014; Robinson et al., 2007).

In Kenya, few women reported sexuality-related concerns as one of their main problems in response to the PSYCHLOPS. In Pakistan, no one reported this as a problem. Self-evaluation, like self-liking or self-esteem, was also seldom reported as a main problem in Kenya and Pakistan. This could perhaps owe to a less sexually conservative culture in the UK and to comparatively lower levels of mental health stigma than in Kenya and Pakistan. Finally, from the description of the PSYCHLOPS categories devised in the UK studies (Ashworth et al., 2007; Lawton et al., 2014; Robinson et al., 2007), it seems the people in Pakistan have labelled a wider range of problematic emotions than those under study in the UK (where coded categories were diagnostic labels or unhappiness). It seems the self-reflective or introspective categories used in response to PSYCHLOPS in the UK were more clinical and less lay formulations of emotional distress (including psychological mechanisms such as self-esteem). This could reflect comparatively higher mental health literacy levels or service contact among primary care users in the UK, who may have more exposure to and therefore be more familiar with such vocabulary (the crossover of lay and professional narratives is referred to as ''proto-professionalism'' in one of the UK studies; Robinson et al., 2007).

When we compared the findings from the PSYCHLOPS to the concepts covered by the nomothetic measures used in the studies, we observed that those nomothetic measures did not capture the most frequent person-generated problem in both countries. Though physical health problems are briefly covered in the context of functioning in the WHODAS, none of the nomothetic measures used in Pakistan had an item specifically on headache, the most frequent problem response in Pakistan. None of the Kenya nomothetic scales used had any items about financial hardship, the most frequent problem response in Kenya.

The WHODAS items were in line with many of the responses gathered for the PSYCHLOPS item on functions the participants found hard to do, in both Kenya and Pakistan: not being able to carry out household responsibilities and usual responsibilities or work. This supports the content validity of the WHODAS in these two contexts, which is expected, given that the WHODAS was developed for international use.

Limitations of the study

As discussed above, social or environmental biasing may have introduced some level of information bias, particularly in the Pakistan site. Some participants reported to the PM + facilitator that they had not told the assessor who carried out the pre-intervention assessment their actual main problem, citing instead another problem they felt more comfortable to discuss.

It seems that in some cases the participants may have misunderstood the questions in the PSYCHLOPS, providing multiple responses for a single item, or citing a further problem in response to the question about activities that are hard to do. This suggests that using the PSYCHLOPS in an interview could benefit from further guidance to assessors, such as a semi-structured interview protocol, in order to ensure that participants understand the questions.

The final, English qualitative data used for analysis may be less rich than the original participant responses. In both study sites, participants gave detailed accounts of their life problems and the

causes and feelings associated with these. The assessor wrote a synopsis of the response and then this synopsis was translated into English. We considered the first listed problem as the main problem response. Although this potential misinterpretation of the original meaning through summary, translation, and coding may have introduced some degree of measurement error, bias seems unlikely because the process is not prone to a systematic or differential misclassification of the reported problems into the overarching themes.

Some of the responses were vague and potentially not mutually exclusive (e.g., Q3a response codes about things that are hard to do included ‘‘daily tasks,’’ ‘‘chores,’’ ‘‘work,’’ and ‘‘providing for the family’’; we coded these responses separately into four distinct themes although some degree of overlap between them may exist).

Implications of the results

Because the conventional nomothetic outcome measures used in the studies did not tap into all participant-identified problems, the use of PSYCHLOPS in conjunction with nomothetic mental health measures can potentially improve outcome studies of mental health interventions.

The possible social desirability effects are a major limitation of this study. Nonetheless, in formative work (pre-trial) and as part of local adaptation of programmes or interventions, important local problems should be identified with the aim to add or tailor specific elements of support to mental health interventions to help alleviate these problems (e.g., employment coaching or livelihood support; Nakimuli-Mpungu, Wamala, Okello, Alderman, Odokonyero, Musisi, . . . Mills, 2014; Nakimuli-Mpungu, Wamala, Okello, Alderman, Odokonyero, Musisi, & Mojtabai, 2014).

Discussion among the study teams has highlighted a benefit of using PSYCHLOPS, in that it provides a more contextualised outcome measure. However, it may or may not be more sensitive to change than nomothetic measures. The PSYCHLOPS provided a very useful tool to initiate the discussion on psychosocial aspects of health problems. The team noted that the PSYCHLOPS was a useful tool for bringing up the items of greatest personal significance for recipients of health care provision, rather than items that may be important to health care providers. This may have helped to ensure that psychological distress was recognised as important and warrants attention from the health system. Further, the Kenya team expressed the view that the PSYCHLOPS was useful as a training and supervision tool for helpers, ensuring they remained focused and explored the person’s issues as they related to self-identified problems.

It is important to consider the use of PSYCHLOPS with some interview guidance to ensure that questions are being answered with one response only, and that in during- and post-intervention PSYCHLOPS responses, the participant reflects on pre-intervention responses in the intended way.

Conclusion

We have gained insight into operational considerations for using the PSYHCLOPS and into important perceived problems in two diverse communities in middle income countries. The PSYCHLOPS has demonstrated that PGOMs can capture concepts that differ from those captured in nomothetic mental health outcome measures. The PSYCHLOPS seemed to have brought added value to two large RCTs on psychological interventions for common mental disorders. However, the use of PSYCHLOPS in these diverse settings has highlighted the need for some specific guidance on how to use it as an interview measure. Users should consider the implications of response biases when using PSYCHLOPS, as they should when applying conventional measures.

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Declaration of Conflicting Interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

The project was approved locally by the Institutional Review and Ethics Board of the Postgraduate Medical Institute, Lady Reading Hospital, Peshawar, Pakistan; the Great Lakes University of Kisumu, Kenya; and by the World Health Organization Ethics Review Committee (ERC; proposal file numbers RPC656 and RPC627). Ethics protocols were submitted to the WHO ERC and the local ERC in parallel, first for the pilot studies, and were then amended to cover the full RCT study. The permission to translate, adapt, and use PSYCHLOPS was formally obtained from the developers of the instrument before the study was conducted.

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Informed consent

Informed consent was obtained from all individual participants included in the study.

Supplementary materials

Supplement 1.

Example of the pre- intervention PSYCHLOPS questionnaire as used in the study sites

Psychological Outcome Profiles Questionnaire (PSYCHLOPS – Pre-intervention version)[4]

Instructions in **bold** are to be read to the client. Instructions in *italics* are for the assessor only.
The following is a questionnaire about you and how you are feeling. First, I will ask you some questions about the problems you are currently experiencing. Please think about these problems no matter how big or small they may be.

Question 1

a. **Choose the problem that troubles you most.** Record a brief summary of the client's description of the problem. If necessary, ask: "Can you describe the problem to me?") *(Please write it below.)*

b. **How much has it affected you over the last week?**

1	2	3	4	5
Not at all affected				Severely affected

Question 2

a. **Choose another problem that troubles you.** Record a brief summary of the client's description of the problem. If necessary, ask: "Can you describe the problem to me?") *(Please write it below.)*

b. **How much has it affected you over the last week?** *(Please tick one box below.)*

1	2	3	4	5
Not at all affected				Severely affected

Question 3

[4] 1 The questionnaire, reproduced with permission, is an adapted version of Pre-therapy Version 5 of the PSYCHLOPS. See www.psychlops.org. All rights reserved © 2010, Department of Primary Care and Public Health Sciences, King's College London. This adapted version is different in that (a) it does not ask when the person became concerned about the problem, (b) it asks how people have felt this last week rather than how people have felt in themselves this last week (Q1.4), (c) it probes for a problem description (Q1.1a and Q1.2a), (d) it has additional questions on coping (Q1.1c-1f and Q1.2c-2f).

a. **Choose one thing that is hard to do because of your problem (or problems).** *(Please write it below.)*

b. **How hard has it been to do this thing over the last week?** *(Please tick one box below.)*

1	2	3	4	5
Not at all hard				Very hard

Question 1.4
How have you felt this last week? *(Please tick one box below.)*

1	2	3	4	5
Very good				Very bad

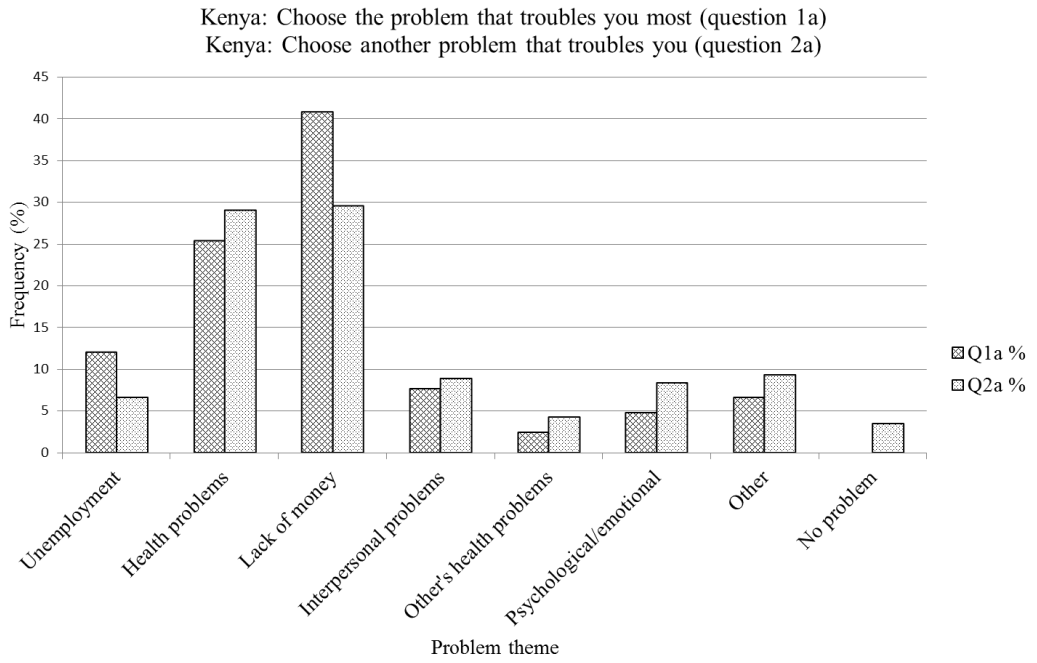
Scoring PSYCHLOPS

- PSYCHLOPS has been designed as a mental health outcome measure. As such, the preintervention score is compared with later scores (during- and post-intervention). The difference is the 'change score'.
- All of the responses in PSYCHLOPS are scored on a six point scale ranging from zero to five. The higher the value, the more severely the person is affected.
- Not every question in PSYCHLOPS is used for scoring. Only the questions relating to Problems (Questions 1.1b and 1.2b), Functioning (Question 3b) and Wellbeing (Question 4) are scored.
- Other questions provide useful information but do not contribute to the change score. PSYCHLOPS therefore consists of three domains (Problems, Functioning and Wellbeing) and four questions which are scored.
- The maximum PSYCHLOPS score is 20
- The maximum score for each question is 5.
- If both Q1.1 (Problem 1) and Q1.2 (Problem 2) have been completed, the total score is: Q1.1b + Q1.2b + Q1.3b + Q1.4.
- If Q1.1 (Problem 1) has been completed and Q1.2 (Problem 2) has been omitted, the total score is: (Q1.1b x 2) + Q1.3b + Q1.4. In other words, the score of Q1.1b (Problem 1) is doubled. This ensures that the maximum PSYCHLOPS score remains 20.

Total PSYCHLOPS Before intervention score: _____

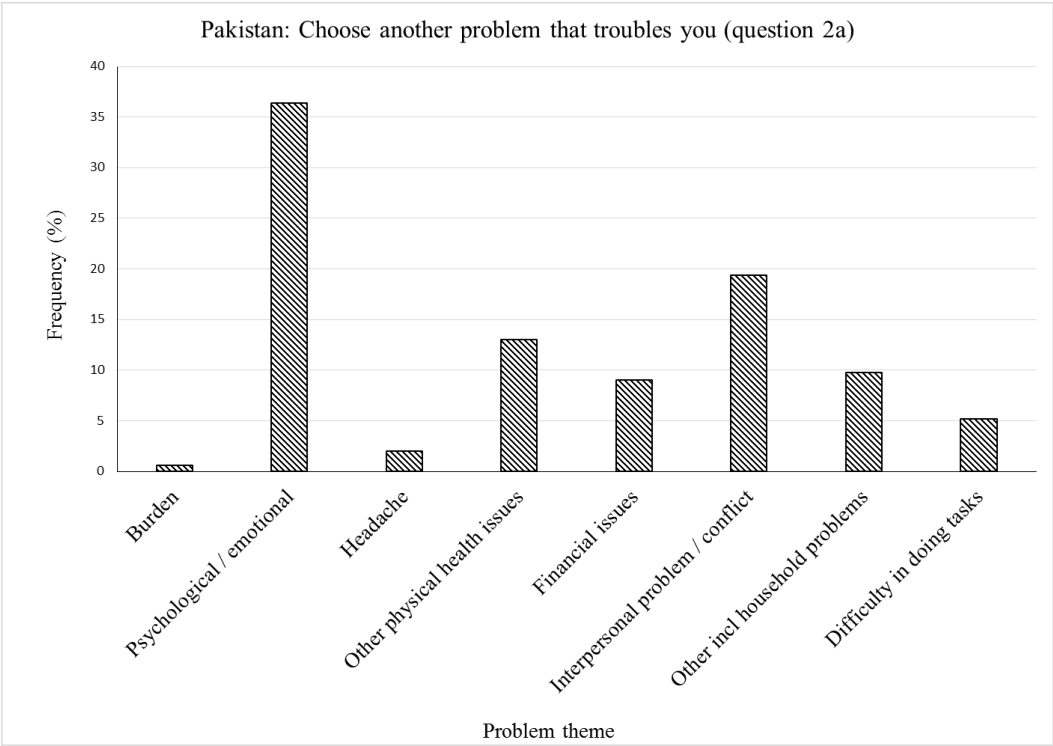
Supplement 2.

Responses to PSYCHLOPS items one and two in Kenya.



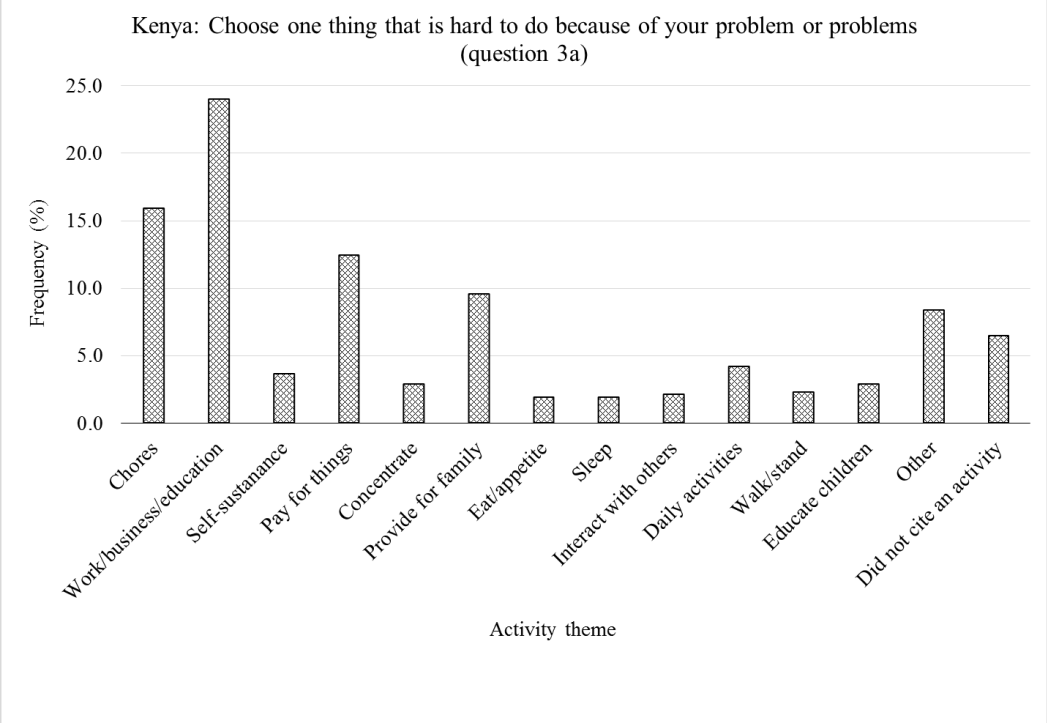
Supplement 3.

Responses to PSYCHLOPS question 2 in Pakistan



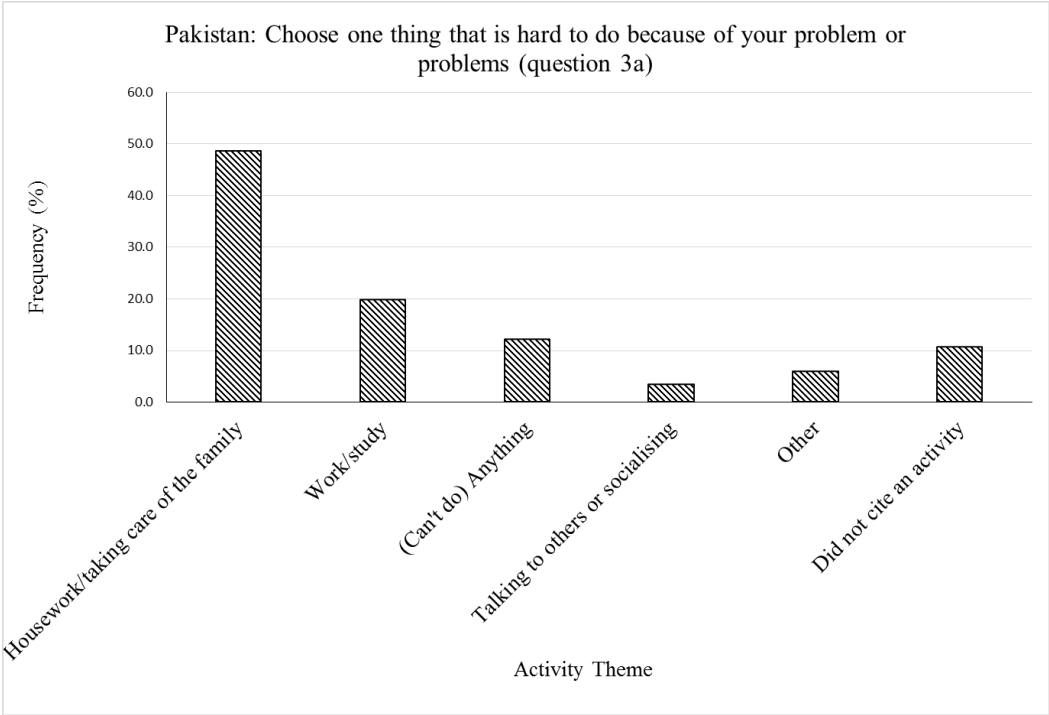
Supplement 4.

Responses to the functioning item in Kenya



Supplement 5.

Responses to the functioning item from Pakistan.



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Chapter 4: Extent and effect of cultural adaptation on self-help interventions – systematic review and meta-analysis

Harper Shehadeh M, Heim E, Chowdhary N, Maercker A and Albanese E. (2016). Cultural Adaptation of Minimally Guided Interventions for Common Mental Disorders: A Systematic Review and Meta-Analysis. JMIR Mental Health. 3, (3): e44

Cultural Adaptation of Minimally Guided Interventions for Common Mental Disorders: A Systematic Review and Meta-Analysis

Abstract

Background: Cultural adaptation of mental health care interventions is key, particularly when there is little or no therapist interaction. There is little published information on the methods of adaptation of bibliotherapy and e-mental health interventions.

Objective: To systematically search for evidence of the effectiveness of minimally guided interventions for the treatment of common mental disorders among culturally diverse people with common mental disorders; to analyze the extent and effects of cultural adaptation of minimally guided interventions for the treatment of common mental disorders.

Methods: We searched Embase, PubMed, the Cochrane Library, and PsycINFO for randomized controlled trials that tested the efficacy of minimally guided or self-help interventions for depression or anxiety among culturally diverse populations. We calculated pooled standardized mean differences using a random-effects model. In addition, we administered a questionnaire to the authors of primary studies to assess the cultural adaptation methods used in the included primary studies. We entered this information into a meta-regression to investigate effects of the extent of adaptation on intervention efficacy.

Results: We included eight randomized controlled trials (RCTs) out of the 4911 potentially eligible records identified by the search: four on e-mental health and four on bibliotherapy. The extent of cultural adaptation varied across the studies, with language translation and use of metaphors being the most frequently applied elements of adaptation. The pooled standardized mean difference for primary outcome measures of depression and anxiety was -0.81 (95% CI -0.10 to -0.62). Higher cultural adaptation scores were significantly associated with greater effect sizes (*P*=.04).

Conclusions: Our results support the results of previous systematic reviews on the cultural adaptation of face-to-face interventions: the extent of cultural adaptation has an effect on intervention efficacy. More research is warranted to explore how cultural adaptation may contribute to improve the acceptability and effectiveness of minimally guided psychological interventions for common mental disorders.

Introduction

Globalization of Minimally Guided Interventions

There is an alarming mismatch between the prevalence of mental disorders and the availability of services to meet mental health needs, particularly in low- and middle-income countries (LMICs) [1]. The Movement for Global Mental Health [2] emphasizes increasing the coverage of treatments for

mental disorders worldwide, particularly in countries where the *treatment gap* is greatest (ie, in low- and middle-income countries) [3]. There is a growing interest in how to deliver psychological interventions to diverse populations, and various innovative solutions may expand their reach and accessibility in low- and high-income countries alike.

Evidence shows that minimally guided interventions (i.e. self-help and guided self-help) may be as efficacious as face-to-face interventions for the treatment of a broad range of common mental disorders [4], including in routine care [5], with guided self-help being slightly superior to complete self-help [6]. Indeed, the World Health Organization (WHO) has updated recommendations on the treatment of depression in low-resource settings to include both face-to-face (eg, high therapist investment) and self-help interventions [7].

Bibliotherapy (ie, therapeutic books) and e-mental health are established means of providing minimally guided psychological interventions requiring one hour or less of face-to-face support time or up to 90 minutes total telephone or email support [8]. They may also appeal to people who are concerned about stigma associated with accessing mental health services. However, evidence on their efficacy is currently limited to high-income countries (HICs) and in culturally homogenous groups [9,10]. A recent systematic review found only three studies on e-mental health interventions in LMICs [11]. Nevertheless, these types of interventions may be viable solutions to narrow the mental health treatment gap in LMICs [12,13], where two-thirds of the billion people using the Internet live [14], and where literacy rates are rapidly rising—currently estimated at 85% of the world population [15]. An important consideration is that in areas with restricted resources and as a means of increasing coverage of minimally guided interventions, the guidance may be given by a trained layperson, such as a family carer [16] or a community volunteer.

Intervention developers and care providers should ensure that treatments are suited to the culture of the intended users, both for moral reasons and for technical, efficacy-related reasons [16]. Cultural adaptation is defined as "the systematic modification of an evidence-based treatment or intervention protocol to consider language, culture, and context in such a way that it is compatible with the client's cultural patterns, meanings, and values" [17]. Cultural adaptation to the needs and expectations of intended users is likely very important for minimally guided interventions because there is little or no therapist interaction to carry the dimension of culture into the intervention.

The Bernal and Sáez-Santiago framework was proposed in 1995 as a framework for planning and conducting interventions with culturally and linguistically diverse (CALD) clients [18,19]. It has eight elements of adaptation: (1) language, (2) person (client) attributes, (3) metaphors, (4) content, (5) concepts, (6) goals, (7) methods, and (8) context of the intervention or services [19].

Evidence suggests that culturally adapted interventions may be more efficacious than interventions that have not been adapted [20], and that effectiveness increases with the number of implemented adaptation elements, according to the Bernal and Sáez-Santiago framework [21,22]. Evidence from systematic reviews show that the extent to which face-to-face interventions are culturally adapted varies considerably [23,24]. However, little is known about the methods and potential benefits of cultural adaptation of minimally guided interventions designed to improve the mental health and

well-being of CALD populations.

The aim of this paper was to understand the extent and effects of cultural adaptation of minimally guided interventions for the treatment of common mental disorders. We conducted a systematic review and meta-analysis of experimental studies of minimally guided interventions for the treatment of common mental disorders—depression, anxiety, and adjustment disorders—conducted with culturally diverse populations. We also tested whether the characteristics and extent of cultural adaptation of the minimally guided interventions under study were associated with the combined effect estimates.

Methods

The methods and procedures used to conduct the systematic review and meta-analysis are reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement [25].

Systematic Search

We designed our search strategy by combining relevant acronyms and synonyms that captured the population, intervention, comparator, and outcomes (PICO) elements, and the study design consistent with our study aim. Professional librarians from the University of Geneva and the University of Zurich assisted in testing and refining the search strategy, which was written for PubMed and adapted to Embase, the Cochrane Library, and PsycINFO.

We conducted a database search of Embase, PubMed, Cochrane Library, and PsycINFO. Four search concepts were combined in order to capture relevant literature: mode of delivery (eg, mobile phone, multimedia, and Web based), intervention program (eg, self-help, minimally guided, and Internet cognitive behavioral therapy [iCBT]), common mental disorders (eg, depression, anxiety, stress, and trauma), and cultural diversity. In order to identify culturally diverse populations, we took a proxy of LMICs classified according to the World Bank [26], using their names and population adjectives with additional high-income country and population names that we considered to be culturally divergent from North America, Europe, and Australia (eg, Saudi Arabia).

Searches were limited to experimental reports found in journal articles published between January 1995 and July 2015. Limits for *humans* were flexibly applied in the electronic searches in PubMed and PsycINFO, though unindexed articles were captured by removing the *humans* filter from 2013 onwards. Details of the search strategy can be found in Appendix 1.

In addition, we hand searched citations of eligible articles, and forward citation of protocol articles found in the search, in order to identify additional relevant published studies. Finally, at the third conference of the *European Society for Research on Internet Interventions* in Poland in September 2015, where we presented preliminary review results, we asked the audience of experts in e-mental health interventions to inform us if they were aware of any articles that we may have missed. All citations were managed using EndNote X7 (Thomson Reuters) and references and abstracts were

exported into Microsoft Excel for easy title and abstract screening.

Study Selection

The inclusion criteria applied to articles to be included in this study are shown in Textbox 1.
The exclusion criteria applied to articles to be excluded from this study are shown in Textbox 2.

Two researchers (EH and MHS) independently screened titles and abstracts according to the inclusion and exclusion criteria, which were then applied to the full texts of the eligible publications. All disagreements were discussed and resolved. Where it did not become clear from the full text, we wrote to investigators to verify the eligibility of the primary study, focusing in particular on whether the intervention was minimally guided and adapted for, not developed for, culturally and linguistically diverse populations.

Textbox 1. Inclusion criteria for articles.

Population:

- More than 75% of participants above a clinical cutoff for symptoms of unipolar depression or anxiety including trauma-related disorders, irrespective of the clinical measure used
- People culturally and linguistically different to those for which the intervention was originally designed

Intervention:

- A minimally-guided or unguided self-help program; one hour or less of face-to-face health worker or trained layperson time or up to 90 minutes total telephone or email support [8], regardless of delivery mode
- Structured and active therapeutic modality (ie, the intervention has clear theoretical underpinnings or an evidence base)
- Must include methodology used (ie, an observational or controlled study, process report, or a protocol)

Comparator:

- Any control condition, including placebo, treatment/care as usual, waitlist control, or active treatment comparison

Outcome:

- Postintervention measures of symptoms of mental illness

Study design:

- Randomized or non-randomized experimental studies

Textbox 2. Exclusion criteria for articles.

- Intervention(s) as an adjunct to traditional face-to-face therapy
- Delivered in an inpatient setting
- Intervention designed for the culturally and linguistically diverse (CALD) population, therefore not adapted
- Training materials for health workers
- Prevention programs for mental disorders

Data Extraction and Additional Data Collection

Two researchers (EH and MHS) designed and piloted a data extraction tool by considering all study characteristics related to the research question considering the PICO elements.

Consistent with the Cochrane Collaboration approach and the methods used in a recent review of cultural adaptations of traditional psychological interventions [24], we developed a structured checklist to critically appraise the methodological quality of the included studies considering the following four criteria: method of randomization, allocation concealment, blinding of outcome assessment, and attrition bias [24]. Two researchers (EH and MHS) independently applied the checklist to each of the included primary studies and a third researcher (EA) was called upon in cases of discordance of opinion.

In order to find out more about cultural adaptation methods used by researchers, we developed a short online questionnaire based on the framework by Bernal and Sáez-Santiago [19] (see Appendix 2) and asked the authors of the included studies to complete it. Based on the information from the full-text articles and the questionnaires received, we assigned each study a score according to the number of Bernal and Sáez-Santiago framework adaptation elements that were applied.

Data Analysis

We retained only the outcome measure designed as the primary endpoint in each study. We entered the number of participants, post-intervention means and standard deviations, and the number of adaptation points into Stata 13 (StataCorp LP) [27]. Then we stratified the analyses by the adaptation score and conducted a meta-analysis using a random-effect method to calculate the pooled effect size based on the combination of the standardized mean differences of primary studies, and formally assessed and quantified heterogeneity using Higgins' I^2 [28]. We then examined whether the extent of cultural adaptation explained the heterogeneity across studies using an unadjusted random-effects meta-regression model.

In a sensitivity analysis, we tested the robustness of using primary outcomes data only for our main analysis by rerunning the meta-analysis separating depression and anxiety data, irrespective of whether measures were used as primary or secondary endpoints. We then compared the I^2 values and 95% CIs between models to gain insight into the potential contribution of the primary versus secondary outcome to the heterogeneity observed in the stratified analyses.

Results

Systematic Search and Study Selection

We identified 4911 records, and excluded 1125 duplicates and 3585 citations on the basis of their titles and abstracts, which left 101 publications that were taken forward for full-text review. Of these, 11 were conference abstracts only, leaving 90 full texts to screen. Two articles were in Korean, so a Korean-speaking acquaintance of the research team was given guidance as to how to screen the articles, neither of which met inclusion criteria [29,30].

Reasons for exclusion are reported in Figure 1. Briefly, several articles did not meet various inclusion criteria, examples of which follow: they were not interventions designed in the West and adapted for a CALD population, but instead were designed specifically for the population [31-33]; the participants were not considered a CALD population [34-36]; the interventions were not self-help according to our standard definition above [37-39]; and/or no common mental disorder outcome measure was reported [40-42].

A total of 12 articles were retrieved (see PRISMA diagram in Figure 1); eight were randomized controlled trials (RCTs), two were protocols for included RCTs [43,44], and one was a protocol for an RCT whose results have not yet been published [45]. One additional article [46] utilized one of the datasets already included [47] (ie, urban sample). One of the included RCTs [47] had two different study sites—urban and rural—with different methodologies; therefore, we treated these as two different datasets. Four studies investigated the effect of bibliotherapy [47-50], and the remaining four were of e-mental health interventions [51-54].

One additional unpublished dataset was identified from key informants at the European Society for Research on Internet Interventions (ESRII) conference, but this was excluded. Upon contacting the author, there was insufficient information to determine whether the intervention was designed for the CALD population and, therefore, whether the study met our inclusion criteria. Characteristics of the studies are presented in Table 1.

There were eight RCTs, including nine datasets for analysis. The cultural backgrounds of the participants included in the studies were Chinese, Romanian, Pakistani, Japanese, and Turkish. Most of the interventions had a cognitive behavioral approach [48,50-52]; however, one study used a problem solving approach [44], one study with two datasets used a social cognitive theory approach [47], and one study used acceptance and commitment therapy [53]. The duration of interventions ranged from 4 to 12 weeks and only two out of eight interventions were completely self-help (ie, no

guidance from a health worker) [53]. The number of Bernal and Sáez-Santiago framework adaptation points carried out ranged from 0 to 7, out of a possible 8. Two interventions, across three datasets, focused primarily on anxiety symptoms, and six on depressive symptomatology, with a range of outcome measures to quantify effects

Data Extraction and Additional Data Collection

We determined the overall risk of bias of the included studies to be moderate. The main issue that introduced potential bias into studies was the outcome measures being subjective self-report measures, coupled with the fact that participants could not be blinded. Details on risk of bias assessment are reported in Appendix 3.

The cultural adaptation methods used were only minimally reported in the primary publications. Six researchers responded to the questionnaire that we sent. Using questionnaire responses, where provided, and the full texts of the RCTs plus any protocols or related previously published studies, we assigned each RCT an adaptation score according to the number of Bernal and Sáez-Santiago framework adaptation elements that we deemed were applied (see Figure 2). In some cases, researchers had considered an element of adaptation but chosen not to carry out that adaptation having not identified a need for it. These were coded as affirmative responses; examples of affirmative questionnaire responses can be found in Appendix 4. All but two researchers indicated that they had translated their interventions into the language of the target group. Seven researchers—five in e-mental health interventions—reported the use of adapted metaphors, using symbols, concepts, idioms, and sayings from the target culture. Local values and traditions in order to carry the content of the intervention were considered by five researchers—four in e-mental health interventions. Theoretical concepts and constructs were considered by four e-mental health researchers and one bibliotherapy researcher. No researcher reported having considered treatment goals in the adaptation of their intervention. The delivery method of the intervention (eg, making particular allowances or breaking strategies into smaller tasks) was mentioned in the questionnaire response of three researchers—two e-mental health interventions. The socioeconomic and political context of the intervention was considered by five researchers—two e-mental health interventions—yet most researchers who responded to the qualitative element of this question mentioned that e-mental health or bibliotherapy in itself was used in response to the socioeconomic and cultural environment (eg, stigma and access to services).

Figure 1. Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram with systematic search and selection process. RCT: randomized controlled trial.

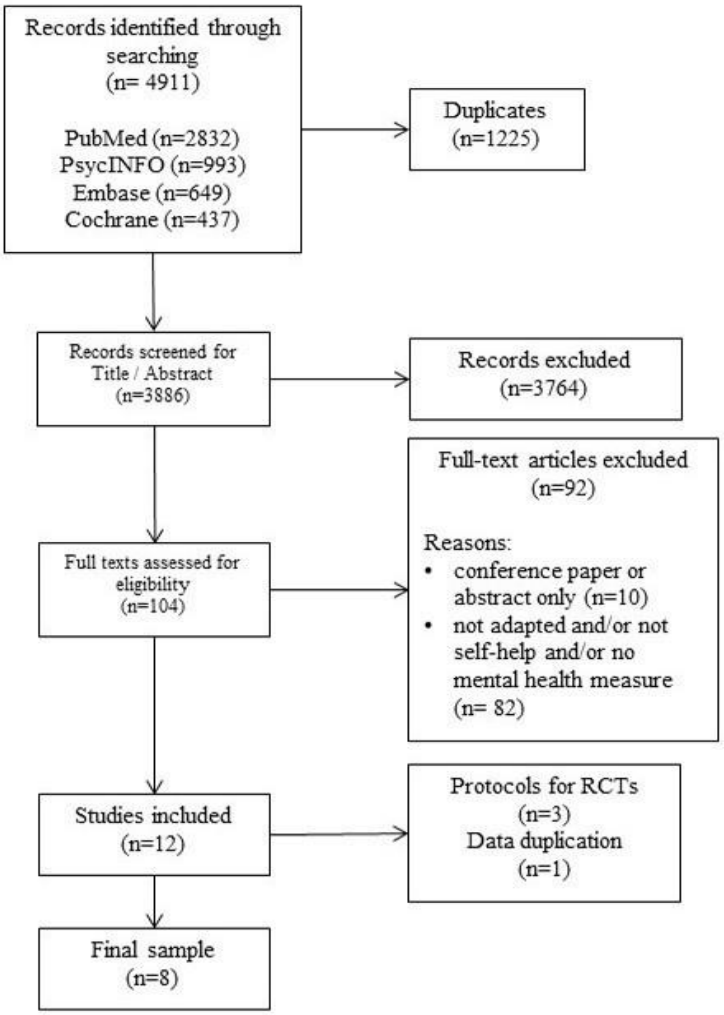

Records identified through searching
(n= 4911)
PubMed (n=2832)
PsycINFO (n=993)
Embase (n=649)
Cochrane (n=437)
Duplicates
(n=1225)
Records screened for Title / Abstract
(n=3886)
Records excluded
(n=3764)
Full texts assessed for eligibility
(n=104)
Full-text articles excluded
(n=92)
Reasons:
• conference paper or abstract only (n=10)
• not adapted and/or not self-help and/or no mental health measure
(n= 82)
Studies included
(n=12)
Protocols for RCTs
(n=3)
Data duplication
(n=1)
Final sample
(n=8)

Table 1. Characteristics of RCT[a] studies retrieved.

Study	Randomized, n (analyzed, n)	CALD[b] group	Delivery	Therapy approach	Length (weeks)	Guidance	Adapt.[c] points	Primary outcome measure
Choi et al 2012 [48]	63 (51)	Chinese	e-MH[d]	CBT[e]	8	MG[f]	7	(C)BDI II[g] depression
Liu et al 2009 [51]	52 (40)	Chinese	Biblio.[h]	CBT	4	MG	0	(C)BDI II depression
Moldovan et al 2013 [52]	96 (84)	Romanian	Biblio.	CBT	4.5	MG	0	BDI II[i] depression
Muto et al 2011 [53]	70 (42)	Japanese	Biblio.	ACT[j]	8	SH[k]	5	GHQ[l] depression
Naeem et al 2014 [54]	192 (183)	Pakistani	Biblio.	CBT	12	MG	5	HADS-D[m] depression
Tulbure et al 2015 [50]	76 (68)	Romanian	e-MH	CBT	9	MG	5	LSASSR[n] anxiety
Ünlü Ince et al 2013 [49]	96 (56)	Turkish	e-MH	PS[o]	5	MG	5	CES-D[p] depression
Wang et al 2013 [47] (urban)	103 (61)	Chinese	e-MH	SCT[q]	4.5	SH	3	PDS[r] anxiety
Wang et al 2013 [47] (rural)	94 (90)	Chinese	e-MH	SCT	4.5	SH	3	PDS anxiety

[a]RCT: randomized controlled trial.

[b]CALD: culturally and linguistically diverse.

[c]adapt: adaptation.

[d]e-MH: e-mental health.

[e]CBT: cognitive behavioral therapy.

[f]MG: minimally guided.

[g](C)BDI II: (Chinese) Beck Depression Inventory II.

[h]biblio.: bibliotherapy.

[i]BDI II: Beck Depression Inventory II. [j]ACT: acceptance and commitment therapy. [k]SH: self-help.

[l]GHQ: General Health Questionnaire.

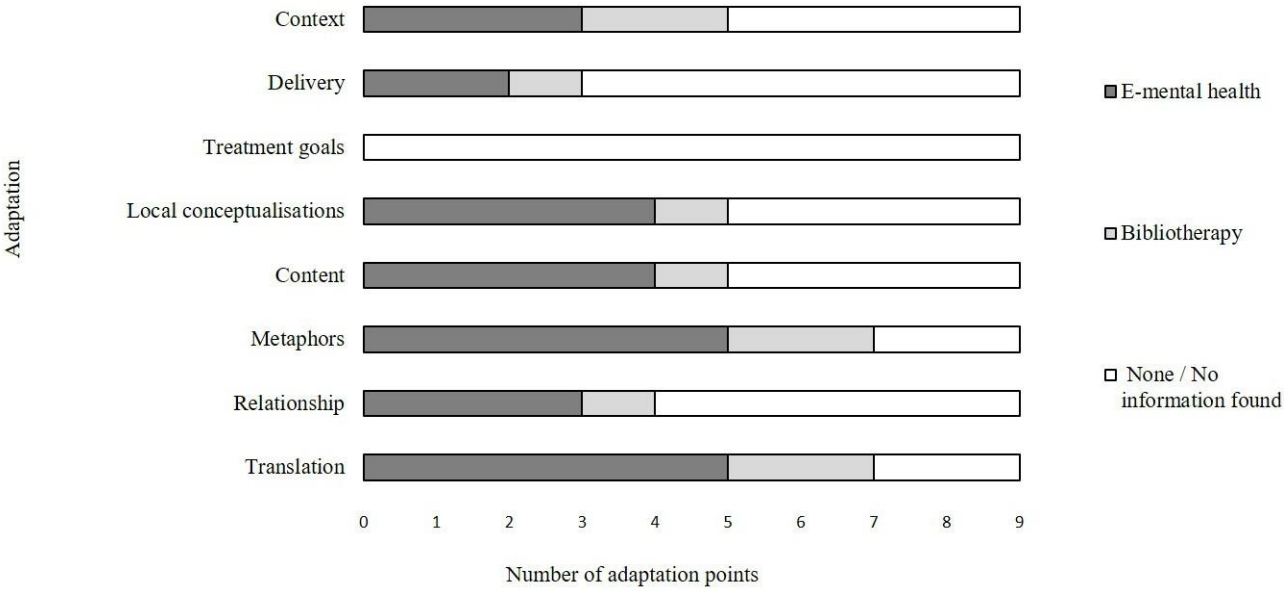
[m]HADS-D: Hospital Anxiety and Depression Scale. [n]LSASSR: Liebowitz Social Anxiety Scale Self Report. [o]PS: problem solving.

[p]CES-D: Center for Epidemiological Studies Depression Scale.

[q]SCT: social cognitive theory.

[r]PDS: Patient Distress Scale.

Figure 2. Adaptation score assigned to the selected studies



Data Analysis

The random-effects meta-analysis (see Figure 3) on the primary outcome measures included nine datasets with a total of 684 participants. We stratified the data by descending assigned cultural adaptation points.

Overall, the minimally guided and self-help interventions significantly improved depression and anxiety symptomatology; the pooled standardized mean difference (SMD) from primary outcome measures was -0.81 (95% CI -0.10 to -0.62), with low-to-moderate between-studies heterogeneity (I^2=28.9%).

The meta-regression (see Figure 4) showed that the adaptation scores significantly explained the pooled SMD. Specifically, a1-point increase in the adaptation score was significantly associated with an increase in effect size of 0.117 (*P*=.04), or a 14% rise in pooled efficacy.

To test the robustness of our main model, which focused on the primary outcome measures, we carried out two separate meta-analyses for each outcome (ie, depressive or anxiety symptoms), irrespective of what the intervention was primarily designed for. Our results were largely unchanged, but the heterogeneity across the studies was greater (SMD=-0.65 [95%

CI -0.92 to -0.38], I^2=62.2% for anxiety and SMD=-0.58 [95% CI -0.93 to -0.24], I^2=75.4% for depression), thus confirming our use of primary measures only in the analysis.

Figure 3. Random-effects meta-analysis of primary outcome measures in order of the study adaptation score. SMD: standardized mean difference.

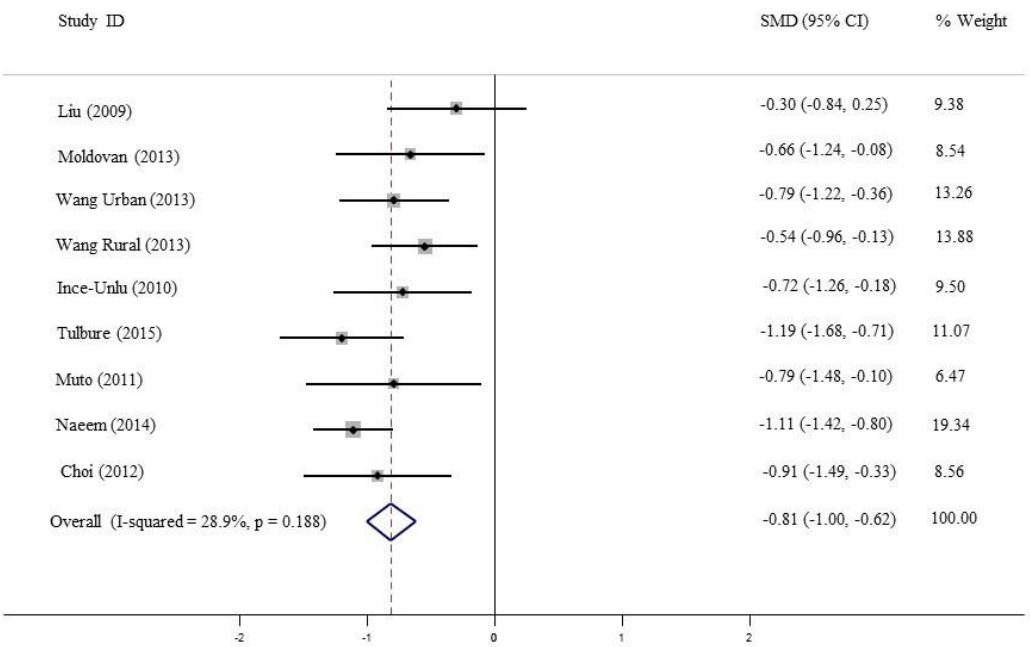
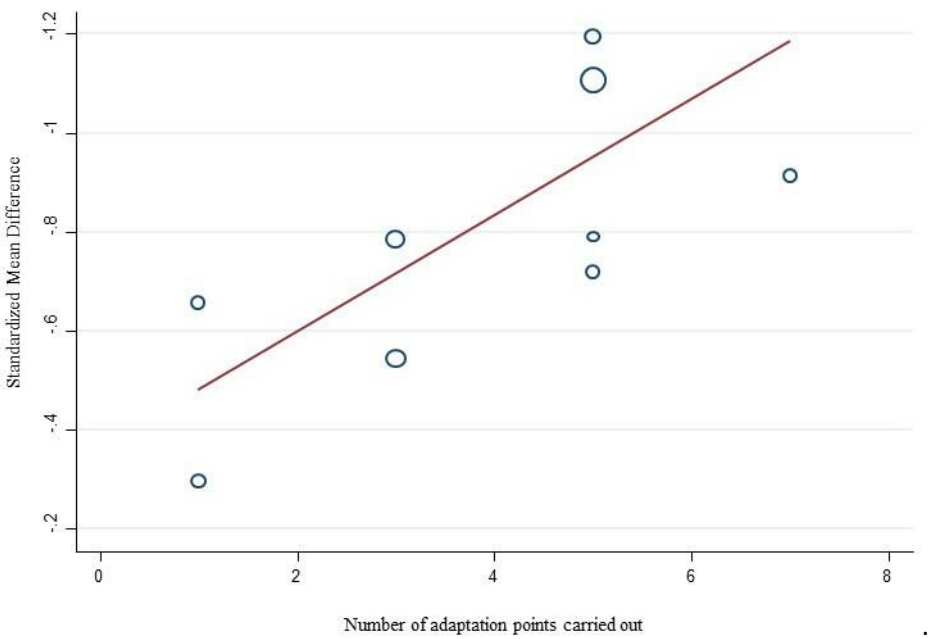


Figure 4. Meta-regression of the standardized mean difference and adaptation score



Discussion

Principal Findings

Culturally adapted self-help or minimally guided bibliotherapy and e-mental health interventions moderately, but significantly, reduced depressive and anxious symptomatology in populations culturally and linguistically distinct from those for which the interventions had been originally designed. More extensive cultural adaptation of the interventions under study was significantly associated with larger effect sizes; however, details of the cultural adaptation methodologies applied were largely underreported.

Researchers should be encouraged to report in detail their adaptation methods to enable readers to appraise both internal and external validity of the study findings, and to inform the implementation of minimally guided interventions and their scalability beyond the research context.

Our results have both public health and clinical relevance, particularly to program managers and health workers who aim to use minimally guided interventions among CALD clients. Decision makers should consider the implications of cultural adaptation on the expected efficacy of interventions before use and, if feasible, plan the required resources and time investments accordingly. A 14% rise in efficacy per adaptation point increase should be weighed against the costs of adapting intervention content, considering the anticipated coverage of the intervention. Adaptation could also positively affect attrition rates, which can be high in self-help interventions.

Our results suggest that the effect of minimally guided interventions used in CALD populations was significantly influenced by cultural adaptation. We were unable to review the specifics of qualitative methodologies involved, but depending on resources, adaptation could resemble a single focus group of community members, or a costly and extensive multi-stakeholder consultation program. Precise information on the methods used is important to allow, on the one hand, a comprehensive adaptation to other settings and contexts and, on the other hand, the preservation of the original intervention's core therapeutic techniques and components to maximize the fidelity to the original intervention.

The Bernal and Sáez-Santiago framework was extremely useful but difficult to operationalize. Further research is needed to develop, pilot, and test an adaptation protocol for minimally guided interventions that would favor the utility and efficiency of the original framework's use in cross-cultural psychology and psychiatry. Such an adaptation protocol should strive to include the target community in qualitative research and discussions on adaptation of materials.

Limitations

Our study has limitations. First, we focused on selected countries that we arbitrarily considered to be culturally distinct. However, this choice was extensively discussed to include geographically diverse LMICs and high-income countries culturally diverse from North America, Australia, and Western

Europe, where the majority of minimally guided interventions are developed and tested. We did not consider potential cultural differences between Western countries (eg, an intervention designed in the United States and used in Norway), and we did not focus on indigenous populations as culturally diverse, and underserved, groups.

Second, and briefly mentioned above, although the meta-analysis showed low heterogeneity across the studies, the meta-regression used to formally explore this further was based on only nine datasets for a total of 684 participants. The Cochrane handbook suggests a minimum of 10 studies to run a meta-regression [55], so these findings should be considered with caution. Further, because half of the studies (n=5) included completers only in their analyses, the reported effect sizes might have been inflated, and an overestimation of the true effect in our meta-analysis cannot be excluded [56]. In addition, the marked differences in intervention duration and in follow-up times between studies may further limit comparability. In the meta-regression, we focused only on the number of Bernal adaptation elements. This was coherent with our main scope and was statistically appropriate (see above). However, other study design characteristics could also explain the between-studies heterogeneity and, at least to some extent, they might even confound or modify the observed effect of cultural adaptation.

Third, using the Bernal and Sáez-Santiago framework carries its own limitations. It was developed over 20 years ago in North America in relation to transcultural issues of working with Latino communities. In addition, it was informed by a theory-driven and anecdotal approach, as opposed to being informed by community-based explorative and qualitative data. We used the Bernal and Sáez-Santiago framework because it had been used to categorize adaptations made in previous systematic reviews [22-24]. The number of elements of the Bernal and Sáez-Santiago framework carried out in each study was based on a subjective assessment of the information from full texts and the qualitative information provided in the questionnaires. Though authors agreed that they had carried out most adaptation elements, the review researchers independently tended to assign lower completion rates. This coding remained subjective on both the authors' and the primary study researchers' part, mainly because Bernal concepts are rather abstract and can sometimes overlap. Also, if researchers stated that they had considered an element but chosen not to carry it out, we coded this as an affirmative answer. A further limitation of the adaptation coding stemmed from the fact that the Bernal and Sáez-Santiago framework was developed for face-to-face treatments. We chose to use the framework in its original state. Some of the categories (ie, treatment goals or therapeutic relationship) are likely less or modestly relevant for minimally guided interventions.

Comparison with prior work

Our results are consistent with evidence from previous systematic reviews on the cultural adaptation of face-to-face interventions for common mental disorders [21-24], particularly that completing more elements of adaptation is associated with a higher effect size [22]. Indeed, the effect size of the most comprehensively adapted, Chinese version of the *Sadness* intervention [48] was similar, if not slightly

higher, compared to its original Australian version [57]—within-groups Cohen's d for reduction in Beck Depression Inventory score was 1.41 in the Chinese adapted intervention and 1.27 in the original Australian version.

Further comparisons with previous findings are less straightforward. Statistical power was limited by the total number of studies included (see below), which were not sufficient to conduct advanced, multivariable, meta-regression models to test which, if any, of the Bernal *adaptation elements* might have contributed the most to the observed between-studies heterogeneity. Similarly, we were not able to consider other plausibly relevant covariates in our models, such as therapeutic modality, level of health worker support, length of delivery, and level of engagement or medium. Evidence on the impact of cultural adaptation is scant, but previous studies found that therapeutic goals, metaphors and symbols [22], and conceptualizations (ie, explanatory models) [21] may significantly account for variance in effect sizes of the interventions under study. These previous findings seem plausible because, although little is known about specific components that determine the effectiveness of a self-help program [9], providing users with an explanatory model of their distress using meaningful terms and symbols may constitute a critical prerequisite of minimally guided interventions.

Conclusions

In conclusion, our results support the careful application of cultural adaptation of minimally guided and self-help interventions, whether provided via bibliotherapy or the Internet, before their use in diverse settings and populations. This largely applies to the *globalization* of mental health services and psychological interventions, for which cultural adaptation is key. Further, there is also a moral case to test and demonstrate the appropriateness, acceptability, and harmlessness of interventions up front. Cultural adaptation is explicitly intended to render interventions meaningful and helpful to groups that are culturally diverse from those for which the intervention was designed. Therefore, these findings may be particularly relevant to program managers and treatment providers in non-Western settings

Acknowledgments

We thank Dr Kieren Egan and Professor Matthias Egger for their advice on statistical analysis of the data.

Conflicts of Interest

None declared.

Appendices chapter 4

Appendix 1. Search strategy

We started by writing a generic search strategy, that was slightly revised for the different databases depending on their indexing terms and medical subheadings system. Guidance was sought from professional librarians where a search concept was problematic. The example systematic search below was that used for pubmed.

Search strategy mode of delivery:
"mobile applications" [MeSH] OR "cell phone" [MeSH] OR telemedicine [MeSH] OR Internet [TIAB] OR multimedia [TIAB] OR multi-media [TIAB] OR online [TIAB] OR computer [TIAB] OR computerized [TIAB] OR computerised [TIAB] OR phone [TIAB] OR smartphone [TIAB] OR Smartphones [TIAB] OR smart-phone [TIAB] OR "web based" [TIAB] OR webbased [TIAB] OR web-based [TIAB] OR "electronic health" [TIAB] OR e-health [TIAB] OR eHealth [TIAB] OR telecare [TIAB] OR telemedicine OR telehealth OR tele-health [TIAB] OR "mobile care" [TIAB] OR m-health [TIAB] OR mHealth [TIAB] OR "mobile-health" [TIAB] OR "mobile health" [TIAB] OR e-mail [TIAB] OR email [TIAB] OR virtual [TIAB] OR cd [TIAB] OR cd-rom [TIAB] OR dvd [TIAB] OR game [TIAB] OR software [TIAB] OR audio [TIAB] OR audiovisual [TIAB] OR video [TIAB] OR media-based [TIAB] OR hypermedia [TIAB] OR ((App) NOT amyloid) NOT atrial) OR apps [TIAB] OR bibliotherapy [TIAB] OR "self-help book" [TIAB]

Search concept intervention:
"self help" [TIAB] OR self-help [TIAB] OR "self change" [TIAB] OR self-change [TIAB] OR self-care [TIAB] OR selfcare [TIAB] OR self-management [TIAB] OR "self directed" [TIAB] OR self-direct* [TIAB] OR self-admin* [TIAB] OR self-instructed [TIAB] OR self-instructional [TIAB] OR self-instruction [TIAB] OR e-therap* [TIAB] OR cCBT [TIAB] OR iCBT OR "minimally guided" [TIAB] OR "minimal guidance" [TIAB] OR therapy [TIAB] OR therapies [TIAB] OR treatment [TIAB] OR intervention [TIAB] OR advice [TIAB] OR program* [TIAB] OR counselling [TIAB] OR counseling [TIAB] OR psychoeducation [TIAB] OR skills [TIAB]

Search concept Common Mental Disorders
Filter 20 years, human:
"Behavioural symptoms" [MeSH] OR "Affective symptoms" [MeSH] OR "Adjustment Disorders" [MeSH] OR "Anxiety Disorders" [MeSH] OR "psychological stress" [MeSH] OR "Obsessive-Compulsive Disorder" [MeSH] OR "Panic Disorder" [MeSH] OR "Phobic Disorders" [MeSH] OR "Stress Disorders" [MeSH] OR "Mood Disorders" [MeSH] OR "Affective Disorders" [MeSH] OR "Depressive Disorder" OR mental [TIAB] OR Adjustment [TIAB] OR Affective [TIAB] OR Anxiety [TIAB] OR post-traumatic [TIAB] OR Panic [TIAB] OR Phobic [TIAB] OR phobia [TIAB] OR Stress [TIAB] OR Mood [TIAB] OR "post-traumatic" [TIAB] OR Affective [TIAB] OR depression [TIAB] OR depressive [TIAB] OR distress [TIAB]

Search concept LAMIC (+ a few other culturally diverse HIC):

Afghanistan OR Albania OR Algeria OR Angola OR Antigua OR Barbuda OR Argentina OR Armenia OR Armenian OR Aruba OR Azerbaijan OR Bahrain OR Bangladesh OR Barbados OR Benin OR Byelarus OR Byelorussian OR Belarus OR Belorussian OR Belorussia OR Belize OR Bhutan OR Bolivia OR Bosnia OR Herzegovina OR Hercegovina OR Botswana OR Brasil OR Brazil OR Bulgaria OR Burkina OR Faso OR Fasso OR Volta OR Burundi OR Urundi OR Cambodia OR Khmer OR Kampuchea OR Cameroon OR Cameroons OR Cameron OR Camerons OR Cape Verde OR African OR Chad OR Chile OR China OR Colombia OR Comoros OR Comoro OR Comores OR Mayotte OR Congo OR Zaire OR Rica OR d'Ivoire OR Ivory OR Cuba OR Djibouti OR Somaliland OR Dominica OR Dominican OR Timor OR Timur OR Leste OR Ecuador OR Egypt OR Arab OR Salvador OR Eritrea OR Ethiopia OR Fiji OR Gabon OR Gabonese OR Gambia OR Gaza OR Georgia OR Georgian OR Ghana OR Grenada OR Guatemala OR Guinea OR Guam OR Guiana OR Guyana OR Haiti OR Honduras OR Hungary OR India OR Maldives OR Indonesia OR Iran OR Iraq OR Jamaica OR Jordan OR Kazakhstan OR Kazakh OR Kenya OR Kiribati OR Korea OR Kosovo OR Kyrgyzstan OR Kirghizia OR Kyrgyz OR Kirghiz OR Kirgizstan OR Lao OR Laos OR Lebanon OR Lesotho OR Basutoland OR Liberia OR Libya OR Macedonia OR Madagascar OR Malagasy OR Malaysia OR Malaya OR Malay OR Sabah OR Sarawak OR Malawi OR Nyasaland OR Mali OR Marshall OR Mauritania OR Mauritius OR Agalega OR Mexico OR Micronesia OR Moldova OR Moldovian OR Mongolia OR Montenegro OR Morocco OR Ifni OR Mozambique OR Myanmar OR Myanma OR Burma OR Namibia OR Nepal OR Antilles OR Caledonia OR Nicaragua OR Niger OR Nigeria OR Mariana OR Oman OR Muscat OR Pakistan OR Palau OR Palestine OR Palestinian OR Panama OR Paraguay OR Peru OR Philippines OR Philipines OR Phillipines OR Phillippines OR Filipino OR Puerto Rico OR Romania OR Rumania OR Roumania OR Russia OR Russian OR Rwanda OR Ruanda OR Kitts OR Nevis OR Lucia OR Vincent OR Grenadines OR Samoa OR Samoan OR Navigator OR Sao Tome OR Saudi Arabia OR Senegal OR Serbia OR Montenegro OR Seychelles OR Sierra OR Leone OR Sri OR Lanka OR Ceylon OR Solomon OR Somalia OR Africa OR Sudan OR Suriname OR Surinam OR Swaziland OR Syria OR Tajikistan OR Tadzhikistan OR Tadjikistan OR Tadzhik OR Tanzania OR Thailand OR Togo OR Togolese OR Tonga OR Trinidad OR Tobago OR Tunisia OR Turkey OR Turkmenistan OR Turkmen OR Uganda OR Ukraine OR Uruguay OR USSR OR Soviet OR Uzbekistan OR Uzbek OR Vanuatu OR Hebrides OR Venezuela OR Vietnam OR Viet Nam OR West-Bank OR Yemen OR Yugoslavia OR Zambia OR Zimbabwe OR Rhodesia OR Polynesia OR Hong Kong OR Isreal OR Macao OR Macau OR Qatar OR Singapore OR Emirates OR Afghan OR Albanian OR Algerian OR Angolan OR Antiguan OR Barbadian OR bajun OR Argentinean OR Armenian OR Aruban OR Azerbaijani OR Aziri OR Bahraini OR Bangladeshi OR Beninese OR Belarussian OR Belizean OR Bhutanese OR Bolivian OR Bosnian OR Herzegovinian OR Batswana OR Brazilian OR Bulgarian OR Burkinabe OR Burundian OR Cambodian OR Khmer Cameroonian OR 'Cape Verdian' OR African OR Chadian OR Chilean OR Chinese OR Colombian OR Comoran OR Mahorais OR Congolese OR Ivoirian OR Cuban OR Djibouti OR Somali OR somalian OR Dominican OR Atoni OR Ecuadorian OR Egyptian OR Arab OR Salvadorian OR Eritrean OR Ethiopian OR Fijians OR Gabonese OR Gambian OR Georgian OR Ghanaian OR Grenadian OR Guatemalan OR Guinean OR Guamanian OR chamorro OR Guyanese OR Haitian OR Honduran OR Hungarian OR Indian OR Maldivians OR Indonesian OR Iranian OR Iraqi OR Jamaican OR Jordanian OR Kazakh OR Kenyan OR Kiribati OR Korean OR Kosovar OR Kyrgyzstani OR Kyrgyz OR Laotian OR Latino OR Lebanese OR Basotho OR Liberian OR Libyan OR Macedonian OR Malagasy OR Malaysian OR Malay OR Malawian OR Malian OR Marshallese OR Mauritanian OR Mauritian OR Mexican OR Micronesian OR Moldovan OR Mongolian OR Montenegrin OR Moroccain OR Mozambican OR Myanmarese OR Burmese OR Namibian OR Nepalese OR Antilles OR Caledonians OR Nicaraguan OR

Nigerian OR Omani OR Pakistani OR Palauan OR Palestinian OR Panamanians OR Paraguayan OR Peruvian OR Filipino Philippino OR 'Puerto Rican' OR Romanian OR Russian OR Rwandan Lucian OR Samoan OR Navigator OR 'Sao Tomean' OR Saudi OR Arabian OR Senegalese OR Serbian OR Seychellois OR 'Sierra Leonean' OR 'Sri Lankan' OR Solomon OR African OR Sudanese OR Surinen OR Swazi OR Syrian OR Tajiks OR Tanzanian OR Thai OR Togolese OR Tonga OR Trinidadian OR Tobagonian OR Tunisian OR Turkish OR Turkmenistani OR Turkmen OR Ugandan OR Ukrainian OR Uruguayan OR Uzbek OR Vanuatu OR Venezuelan OR Vietnamese OR Yemeni OR Yugoslavian OR Zambian OR Zimbabwean OR Rhodesian OR Polynesian OR 'Hong Kongese' OR Israeli OR Macanese OR Qatari OR Singaporean OR Emirati

Appendix 2: Questionnaire sent to researchers on methodology

Dear Colleague,
Many thanks for completing this survey, which will take you approximately 10-15 minutes, depending on the amount of information you wish to provide. Please let us know if you prefer a short telephone interview, in this case, we are happy to call you.
We would like to thank you very much in advance for your help on this important information gathering exercise.

Best wishes,

Melissa Harper and Eva Heim

(If you would like to know more about the design of this survey, it was informed by the following references:
Chowdhary, N., Jotheeswaran, A. T., Nadkarni, A., Hollon, S. D., King, M., Jordans, M. J., . . . Patel, V. (2014). The methods and outcomes of cultural adaptations of psychological treatments for depressive disorders: a systematic review. Psychol Med, 44(6), 1131-1146. doi: 10.1017/s0033291713001785
Bernal, G., & Sáez-Santiago, E. (2006). Culturally centered psychosocial interventions. Journal of Community Psychology, 34(2), 121-132. doi: 10.1002/jcop.20096)

Questions
Question 1. Please tell us more about how you adapted the intervention. Did you adapt the intervention in any of the following ways:

	Yes	No	N/A
1. Did you translate the intervention to local language?			

2. If applicable, did you consider culture in the patient-therapist relationship (e.g., the impact of cultural similarities or differences on therapeutic interactions or disclosures)?			
3. Did you consider metaphors in the cultural adaptation of your intervention (e.g., culturally relevant materials, stories, examples or symbols)?			
4. Did you adapt the content of the intervention to the local environment (e.g., focus on locally relevant stressors, values or customs, incorporation of local practices or additional material to account for local culture)?			
5. Did you adapt the intervention to account for local conceptualisations/idioms of distress of the presenting problem (e.g., somatisation, social roles and norms, spiritual beliefs around the problem)?			
6. Did you attempt to consider treatment goals in relation to cultural knowledge (e.g., treatment aims in relation to values, customs, and traditions)?			
7. Did you adapt the method of delivery or presentation of materials to the local culture (e.g. adapting ethnicity of illustrated people or using spoken word or pictures instead of text-heavy presentations)?			
8. Did you adapt to the broader social, economic, and political context of the user (e.g., consideration of accessibility, feasibility and acceptability of the intervention)?			

Question 2. We would very much appreciate if you could kindly describe the cultural adaptation methods you used for each of the previous questions you marked with "yes".
(Only displayed for methods that were marked before)
1. How did you translate the intervention to local language?

2. How did you consider culture in the patient-therapist relationship?

3. How did you consider metaphors in the cultural adaptation of your intervention (e.g., culturally relevant materials, stories, examples or symbols)?

4. How did you adapt the content of the intervention to the local environment (e.g., focus on locally relevant stressors, values or customs, incorporation of local practices or additional material to account for local culture)?

5. How did you adapt the intervention to account for local conceptualisations of the presenting problem (e.g., somatisation, social roles and norms, spiritual beliefs around the problem)?

6. How did you attempt to consider treatment goals in relation to cultural knowledge?

7. How did you adapt the method of delivery or presentation of materials to the local culture?

8. How did you adapt to the broader social, economic, and political context of the user (e.g., consideration of accessibility, feasibility and acceptability of the intervention)?

Question 3. For the development and evaluation of complex interventions, the Medical Research Council (in the UK) recommends a phased development process consisting of: modeling/theoretical development, formative work, piloting and evaluation. (http://www.ncbi.nlm.nih.gov/pubmed/18824488).

We are interested at what stage of your study you possibly applied cultural adaptation methods. Thank you very much for kindly providing us with any relevant information on these four phases below.

Modelling/theoretical development (e.g., Identifying or developing theory, modelling processes and outcomes)	
Formative research (e.g., cultural research on the target population of the intervention) Pilot or feasibility testing (e.g., testing procedures, estimating recruitment and retention, Determining sample size)	
Evaluation (please describe the design of the evaluation research carried out or planned)	

Question 4. If you have any other comments or information you would like to provide, please add it here:

Appendix 3. Risk of bias of individual studies

	Random sequence	Allocation concealment	Blinding of outcome	Incomplete outcome
Choi 2012	+	+	+	+
Liu 2008	?*	?	+	+
Moldovan 2013	+	+	+	+
Muto 2011	+	+	+	+
Naeem 2014	+	?	+	+
Tulbure 2015	+	+	+	+
Unlu Ince 2013	?*	+	+	+
Wang Urban 2014	+	?	+	+
Wang Rural 2013	+	?	+	+

*Randomisation was reported but with no indication of how it was carried out

Appendix 4: Examples of qualitative questionnaire responses from researchers

1) Relationship with the therapist:
"This was an online depression program so there was minimal direct contact between patient and therapist. Patients were contacted by the therapists weekly to check in on progress, answer any questions, and provide encouragement. During telephone contact with the Chinese participants, the clinicians provided gentle encouragements and reinforced their effort in practicing homework, in contrast to giving explicit praise and reinforcement when working with Western participants."
2) Metaphors:
"- culturally specific idioms known as 成成 Chéngyǔ (four-worded sayings derived from ancient stories or poems that deliver a moral teaching, and forms part of everyday Chinese vocabulary) were used to enhance meaning, e.g. to describe different types of negative thinking styles."
3) Content:
"…explicitly discussing migration and culture by using culture-specific cases and problems that are recognizable for the target group concerned, and including recognizable examples of persons with similar problems (eg, a young woman who migrated 2 years ago and can't find her way in the Netherlands)."

4) Theoretical concepts and constructs:
"No modifications were felt to be necessary in the central concepts of ACT to fit a Japanese reader—the issue was the means of presenting those ideas."
"The term depression itself hasn't been used in the intervention. In fact, all other symptoms of depression were used to make it more recognizable and less stigmatizing for the target group."
5) Delivery method:
"…modified exercises…to fit the Japanese language community."
"Each participant is allowed to choose his/her language of preference."
6) Socio-economic and political context:
"[The book] can be used by the patients or carers with at least 5 years of education."
"Due to lack of Internet service at home in Beichuan, all participants had to complete tests and receive online treatment in the counseling center's computer room."

References chapter 4

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Abbreviations chapter 4

ACT: acceptance and commitment therapy
adapt.: adaptation
BDI II: Beck Depression Inventory II
biblio.: bibliotherapy
CALD: culturally and linguistically diverse
(C)BDI II: (Chinese) Beck Depression Inventory II
CBT: cognitive behavioral therapy
CES-D: Center for Epidemiological Studies Depression Scale
e-MH: e-mental health
ESRII: European Society for Research on Internet Interventions
GHQ: General Health Questionnaire
HADS-D: Hospital Anxiety and Depression Scale
HIC: high-income country
iCBT: Internet cognitive behavioral therapy

LMICs: low- and middle-income countries
LSASSR: Liebowitz Social Anxiety Scale Self Report
MG: minimally guided
PDS: Patient Distress Scale

PICO: population, intervention, comparator, and outcomes
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PS: problem solving
RCT: randomized controlled trial
SCT: social cognitive theory
SH: self-help
SMD: standardized mean difference
WHO: World Health Organization

Chapter 5: Conceptualisation of a scalable, internet delivered intervention for depression (Step-by-Step)

Carswell K., Harper Shehadeh M., Watts S., Heim E., van't Hof E., Abi Ramia J., Wenger A., van Ommeren M. (2018). Step by Step: A new WHO online intervention for depression. mHealth. 4:34

Step-by-Step: a new WHO digital mental health intervention for depression

Abstract

The World Health Organization is developing a range of interventions, including technology supported interventions, to help address the mental health treatment gap, particularly in low and middle-income countries. One of these, Step-by-Step, is a guided, technology supported, intervention for depression. It provides psychoeducation and training in behavioural activation through an illustrated narrative with additional therapeutic techniques such as stress management (slow breathing), identifying strengths, positive self-talk, increasing social support and relapse prevention. Step-by-Step has been designed so that it can be adapted for use in settings with different cultural contexts and resource availability and to be meaningful in communities affected by adversity. This paper describes the process of developing Step- by-Step and highlights particular design features aimed at increasing feasibility of implementation in a wide variety of settings.

Introduction

The increasing availability of smartphones in low and middle-income countries provides an opportunity for addressing the mental health treatment gap which can be as high as 75% but can vary by disorder and region (1). Evidence for online psychological interventions from high income countries has shown that they are effective for depression and anxiety and may show equal benefit to face to face cognitive behavioural therapy (CBT) interventions if they are guided (1,2). Guidance may be limited (e.g., briefly reviewing completion of activities) and can be effective when provided by non-specialists with supervision (3). World Health Organization (WHO) guidelines recommend the use of self-help psychological interventions for depression and non-specialist delivery of interventions more generally (4). Although online interventions may provide a further option for delivery of services where resources are scarce (5), research on the effectiveness of online interventions in low- and middle-income countries is limited (6).

As part of recent work to publish a range of potentially scalable psychological intervention manuals (7), WHO is developing several technology supported psychological interventions for a range of user groups. These interventions aim to be flexible to meet the needs of groups affected by a wide range of adversities including potentially traumatic events and ongoing severe and chronic problems, such as poverty. These technology supported psychological interventions provide potential for greater coverage, particularly in hard to reach, remote or insecure places (e.g., conflict zones) or for individuals who face other barriers or do not wish to access publicly visible services because of stigma. Such interventions may use delivery methods such as pre-recorded self-help provided to a group [e.g., WHO's Self Help Plus intervention) (8)], or minimally guided self- help delivered through a website or a mobile app such as the intervention described in this paper.

This paper describes "Step-by-Step"—an online minimally guided self-help intervention—and outlines

the process of development with regards to four core aspects: Theoretical background, content, guidance model and delivery system. It focuses particularly on elements of the intervention that may make Step-by-Step more suitable for adaptation for use in a range of countries.

Theoretical background of Step-by-Step

Step-by-Step was initially conceptualised as an online self-help version of WHO's Problem Management Plus (PM+). PM+ is a transdiagnostic psychological intervention for common mental health problems comprising of core strategies of stress management, behavioural activation, problem management and increasing social support, which are delivered over five, 90-minute sessions, to groups or individuals (9).

Anecdotal reports from teams implementing PM+ in randomised controlled trials suggested that the problem management strategy needed comparatively more support from facilitators, including in some cases, providing suggestions for ways to address problems. On the basis of this information and feedback from reviews of an earlier version of Step-by-Step, problem management was removed due to concerns this would be a difficult skill to provide via technology, with or without support, to individuals in low and middle-income countries.

The intervention was therefore adapted to focus on depression with behavioural activation as the central therapeutic component with additional components covering psychoeducation, stress management techniques (slow breathing), identifying strengths, positive self- talk, increasing social support and relapse prevention. Behavioural activation was chosen as the central technique as this has been shown to be a highly effective and simple way to address depressive symptoms (10). The additional strategies were included partly to support behavioural activation (e.g., social support as a form of behavioural activation, slow breathing to help overcome anxiety when completing a more challenging activity). While Step- by-Step is mainly based on behavioural activation, the intervention is designed to be flexible enough to allow for additional techniques to be added in the future to make it transdiagnostic (e.g. by adding an exposure or cognitive-restructuring module).

Basing interventions on psychological theory and involving end users in the design process have been proposed as important aspects of intervention development (11). Possible end users of Step-by-Step include individual beneficiaries using the product, as well as governments and agencies that may implement the package once released. The needs of these groups were considered in the design process through consultations with key stakeholders and experts as well as qualitative work with populations in Lebanon (the site of the first pilot) (results to be published in a forthcoming paper). These consultations provided important information which informed the development of the content (e.g., easy adaptation of content), the guidance model (e.g., telephone or email support) and the delivery system (e.g., app or website). Important considerations are explained below in more detail.

Step-by-Step content overview

Existing technology supported interventions use different methods to convey therapeutic information. For example, illustrated content is used in “This Way Up” (https:// thiswayup.org.au) and “Deprexis” (https://deprexis.com), while “Moodgym” (https://moodgym.com.au) uses written text accompanied with interactive activities (e.g., activity planning using an online tool). The content for Step-by- Step is delivered over 5 sessions using a hybrid of these two models with an illustrated narrative story (around 50 slides per session) providing most of the information and an interactive component where users practice the skills they are learning (e.g., activity scheduling). An illustrated story told by an individual experiencing depression, was chosen as the format for delivery as it has previously been shown to be an effective medium for online interventions (12) and can be further adapted by adding audio recordings of the text for areas where literacy may be a problem. A generic English version of the content was created and then subsequently adapted for the first pilot test in Lebanon. Results and lessons learned from the pilot will be published in a forthcoming paper.

The Step-by-Step narrative is based on a character who visits a health worker for help with depression, it is told by the main character with the health worker providing instruction on the therapeutic techniques (*Figure 1*). Depending on the setting, this may be modified to another trusted figure, e.g., community elder. Each session lasts for around 30 minutes and is split into two parts each of approximately 15 minutes. In the first part, the character relays their story, including the skills they learnt from the health professional and their attempts to apply them in their own life. During the interactive part of the session, the health professional character teaches in more detail the core therapeutic component for that session and coaches the user to complete activities for the week using interactive online activities (*Figure 2*).

Figure 1 Character options for Step-by-Step (Lebanon version).

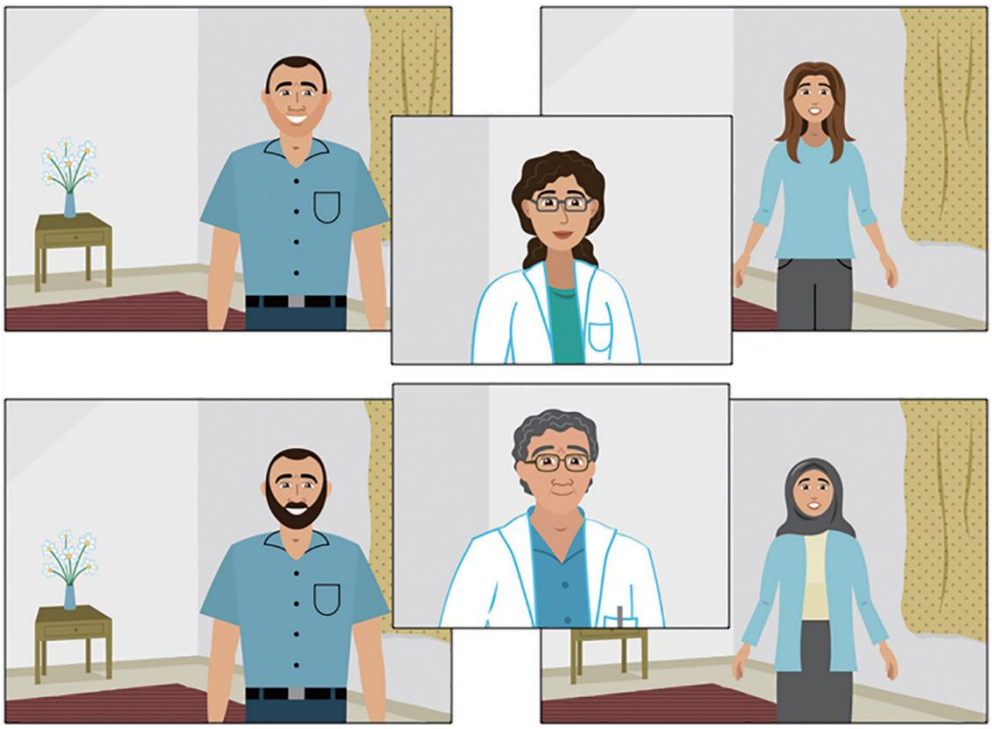
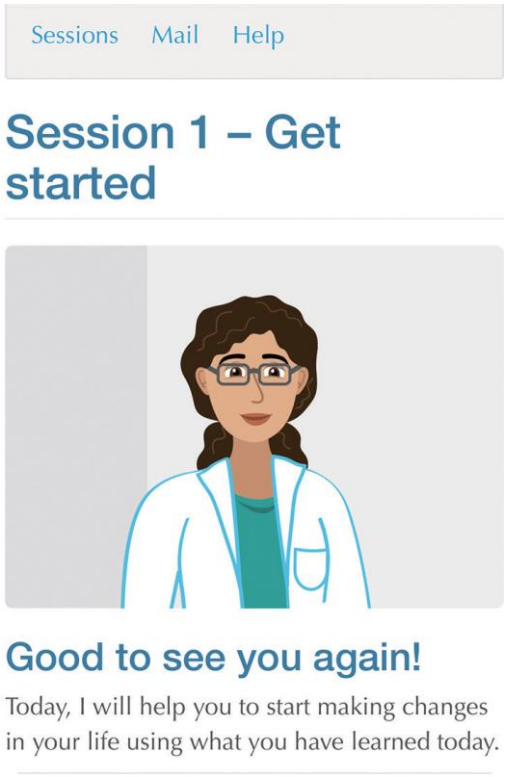


Figure 2 Coaching to complete activities.



The health care professional as the trusted figure was introduced as the Ministry of Public Health in Lebanon and other key stakeholders advised that people would want health information to come from a trusted source, preferably a doctor character. No literature could be found which addresses the status of a doctor within Lebanon to support this decision, but initial user testing of the intervention suggested this character was acceptable, with some further changes made to the appearance of the character in response to feedback from users. The health professional character also provides a narrative device by which to deliver baseline and session by session questionnaires.

Step-by-Step starts with an assessment called “Your Strengths” which includes questionnaires covering mood, functioning and identified problems. A brief exercise to identify individual strengths was also included to provide the user with some form of support from the start of the intervention. Identifying strengths has been proposed as an approach for building resilience in cognitive behavioural therapy (13) and this technique appeared to fit well as a brief and simple exercise to provide support early on in the programme. In addition, it was thought this could potentially provide greater encouragement to users to return for later sessions than if the first session was an assessment only. This exercise was used in user testing and there no concerns were raised by participants. The five therapeutic sessions are: “Get started” (psychoeducation and trying small and pleasant activities), “Get active” (behavioural activation) “Beat obstacles” (more complex behavioural activation with strategies to overcome difficulties such as stress management as a means to combat anxiety about carrying out activities), “Get together” (increasing social support) and “Keep it up” (relapse prevention).

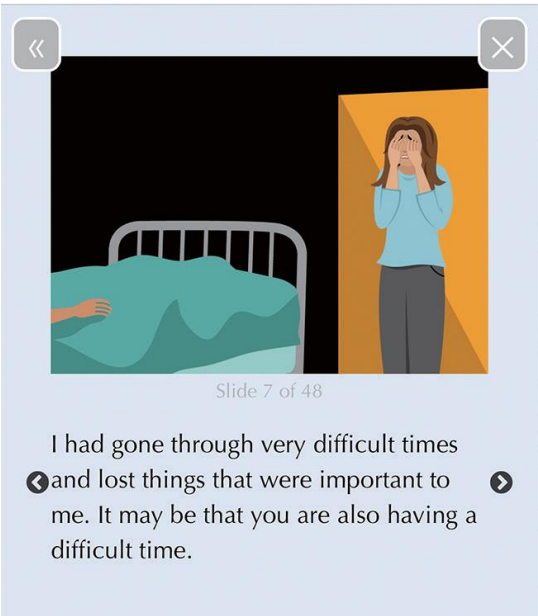
Regarding design considerations, the intervention was designed to maximize accessibility across different socio- economic and education groups. The text of the story is easy to read to aid understanding. Narrated videos of the illustrated texts are available to improve access for people with low literacy. File size for the content was kept as low as possible to facilitate use in areas where internet access may be expensive, or where bandwidth is restricted or unreliable. Tailoring content of interventions to users has been suggested as a design feature of more effective technology supported interventions (14). The story text and images of Step-by-Step were devised to provide some tailoring towards characteristics of the individual (e.g., gender), whilst allowing for wide use within a community by not being overly specific. Minor adaptations can be made to the central storyline to ensure it is suitable for women or men or younger or older age groups. Illustrations are digital which means features or clothing can be easily changed, which should reduce the resources required for illustration adaptation.

In the case of Lebanon, Step-by-Step was tailored to the users' gender and to very broad cultural aspects. It was adapted to have four versions of the main character with users selecting the one they preferred. For women, two options were presented, a woman (called Zeina) with headscarf and without (*Figure 1*), for men, the two options included a character (called Karim) with a beard and without (*Figure 1*). These characters were tested firstly with staff at the Ministry of Public Health and later with community members during the adaptation phase (results to be published in a forthcoming paper).

Another consideration to increase relevance for different populations was ensuring the story and images were not too specific to one group or event. The Lebanese adaptation of Step-by-Step had to be relevant for major cultural groups living in the country (e.g., Syrians, Lebanese and Palestinians), thus focusing on experiences of conflict, for example witnessing a bombing, may increase relevance for one group while reducing relevance for another. Toaddress this the story does not focus on specific events or detailed descriptions of experiences, but instead describes adversity and difficult life events using images that depict or suggest common adversities such as illness and death. The image in *Figure 3* demonstrates this, as it reflects the experience of loss or illness without defining the cause. This may make the image relatable to a wider group of people, as it allows for an individual to speculate on the cause and may thereby increase relevance, as opposed to an image which confirms a cause (e.g., conflict) that may not be so relatable to an individual's own situation. This is an example of a design decision to ensure as wide as possible applicability and to reduce the number of versions required for each setting.

The Step-by-Step content was designed with a view to compatibility across implementation and delivery systems. Therefore, informational (narrative story) and interactive exercises (such as activity scheduling) can conceivably be delivered through many mediums such as a self-help book, website, app or video to fit the needs of a country or context, as long as the core components of the narrative story and interactive activities remain constant.

Figure 3 Ensuring relevance of the central Step-by-Step narrative to many groups.



Guidance model for Step-by-Step

Guidance in Step-by-Step is provided by non-professional "e-helpers" and is limited to 15–20 minutes per week using telephone, synchronous online messaging or through a secure email system. Multiple contact approaches are provided to ensure users have choice and can use a method that suits their needs. E-helpers are university graduates without a professional qualification in mental health care, but with some experience of providing support to vulnerable people (e.g., volunteering, working in a community service). They are trained to provide structured guidance which covers a review of the previous session and any related questions, review of the user's experience putting the skills into practice and providing encouragement and support in using the program. Initial training is brief (an initial six days for the Lebanon pilot) and ongoing managerial and clinical case supervision is provided by qualified staff (e.g., a clinical psychologist). E-helpers are trained to use basic helping skills, like active listening and basic problem management for other issues that might be mentioned by users, for example orientating the person towards other sources of support or help in their community. E-helpers are also trained to identify, assess, manage and report risk, adverse or serious adverse events encountered during the support sessions to the clinical supervisor.

As the content was purposefully designed to be independent of the guidance model, Step-by-Step can potentially be provided using contact on request (ad hoc guidance) or without any guidance, which may be more suited in certain contexts or for those who prefer not to have contact with a person. As a guided self-help intervention, Step-by-Step is flexible enough to fit into multiple types of health and social care systems and adaptable to different settings and resource availability.

Delivery system for Step-by-Step

The initial version of Step-by-Step is a responsive website that automatically resizes for use on mobile devices. A website was first developed as this was deemed a simpler approach for a first version than an app for use in an initial pilot. Importantly, given the increasing use of mobile devices globally, it was essential for the intervention to be designed for use on mobile devices. The client user area of the website comprises of: (I) welcome page; (II) registration process and baseline data collection; (III) a "home" area where each session is displayed, along with an area for reviewing past exercises and inputs. In addition to the client user area, a clinical dashboard for e-helpers and supervisors provides details of client progress, including weekly scores on psychological distress measures and an overview of sessions completed. This section is used to securely record information.

A smartphone app and updated web version of Step- by-Step is under development, which will include further refinements to usability and presentation of the core content. This will bring improvements to the ability to deploy Step-by-Step in areas where internet coverage is poor or expensive, as a Wi-Fi connection can be used to download the app which can then be used without an active connection.

Adapting and using Step-by-Step in other countries and settings

The features of Step-by-Step reported above make it possible to adapt it for other cultures or settings. Research suggests that psychological interventions are likely more effective if they have been adapted for different contexts, for example language, content, local idioms and metaphors (15). Adaptation of Step-by-Step would involve formative research to ensure the storyline and illustrations of Step- by-Step are suitably adapted for different communities. Quite possibly the helper in the story will not be a doctor in a range of countries. The use of digital illustrations may further aid adaptation by allowing changes to only key features of illustrations.

Step-by-Step is designed to be implemented by a government or organization providing coverage to a large population. Adaptations to the story and illustrations, informed by qualitative data gathered from users, have to be made with the support of an illustrator and programmer, with support to implement and manage the online platform. It has been designed as a global public good which WHO will release on the basis of positive results from randomised controlled trials. The flexibility of Step-by-Step means that it can be delivered in many different ways depending on the context.

In upcoming trials, it will be tested both with minimal weekly guidance and in separate trials using contact on request. The trials will use a smartphone app and web version. Once efficacy has been demonstrated, it can then be further researched or implemented in different ways, for example, a healthcare worker could potentially use the story to guide face to face sessions, or different cadres of individuals could be trained to provide remote or face to face support. The conceptualisation of content (the story and exercises), guidance model (e.g., minimal, contact on request or no guidance) and platform (app, website or as a book) as separate but related parts means that Step-by-Step has the flexibility to be used in multiple ways.

Conclusions

WHO has developed an online psychological intervention for people with depression which is

currently being tested in an uncontrolled pilot study in Lebanon. By considering the overall end goal—an adaptable evidence-based intervention system that is scalable in multiple settings—as well as design and psychological theory, the work is leading to several developments that may have implications beyond the Step- by-Step intervention. These include: (I) an understanding of how to develop content that can be deployed in multiple ways depending on resources available and the context; (II) a flexible guidance model that allows for an intervention to be used with no or different intensities of guidance; (III) the prospect of a delivery platform that can be used with other interventions of a similar format (e.g., narrative story and interactive exercises); (IV) a system that is expandable to include other therapeutic components. The next steps are to test the smartphone app and web version of the intervention in at least two randomized controlled trials and learn further about efficacy and feasibility of implementation following the Medical Research Council's Guidance on developing complex interventions (16).

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

Informed Consent: Informed consent is not required because data collected and provided could not be tracked back to individuals.

Disclaimer: The opinions expressed in this paper are those of the authors and do not necessarily represent the decisions, policies, or views of the WHO.

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Chapter 6: Cultural and contextual adaptation of Step-by-Step

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Community cognitive interviewing to inform local adaptations of an e-mental health intervention in Lebanon

Abstract

Background.

Lebanon has a need for innovative approaches to increase access to mental health care to meet the country's current high demand. E-mental health has been included in its national mental health strategy while in parallel the World Health Organization has produced an online intervention called 'Step-by-Step' to treat symptoms of depression that is being tested in Lebanon over the coming years.

Aim.

The primary aim of this study is to conduct bottom-up, community-driven qualitative cognitive interviewing from a multi-stakeholder perspective to inform the cultural adaptation of an Internet-delivered mental health intervention based on behavioural activation in Lebanon.

Methods.

National Mental Health Programme staff conducted a total of 11 key informant interviews with three mental health professionals, six front-line workers in primary health care centres (PHCCs) and two community members. Also, eight focus group discussions, one with seven front-line workers and seven others with a total of 66 community members (Lebanese, Syrians and Palestinians) were conducted in several PHCCs to inform the adaptation of Step-by-Step. Results were transcribed and analysed thematically by the project coordinator and two research assistants.

Results.

Feedback generated from the cognitive interviewing mainly revolved around amending the story, illustrations and the delivery methods to ensure relevance and sensitivity to the local context. The results obtained have informed major edits to the content of Step-by-Step and also to the model of provision. Notably, the intervention was made approximately 30% shorter; it includes additional videos of content alongside the originally proposed comic book- style delivery; there is less emphasis on total inactivity as a symptom of low mood and more focus on enjoyable activities to lift mood; the story and ways to contact participants to provide support were updated in line with local gender norms; and many of the suggested or featured activities have been revised in line with suggestions from community members.

Conclusions.

These findings promote and advocate the use of community-driven adaptation of evidence-based psychological interventions. Some of the phenomena recorded mirror findings from other research about barriers to care seeking in the region and so changes made to the intervention should be useful in improving utility and uptake of 'Step-by-Step'.

Introduction

E-mental health (i.e. the use of Internet and mobile phones for delivering mental health treatment) has enormous potential to increase access to evidence- based interventions for mental and behavioural disorders, particularly in middle-income countries with wide smartphone use and Internet coverage such as Lebanon (Arjadi *et al*. 2015). Lebanon is a small country with a high mental health care need due to a history of conflict and political unrest, an under-resourced system and an influx of almost 1.5 million Syrian refugees (UNHCR, 2018). Estimates from 2006 suggest that just 10% of people in Lebanon who had a mental disorder had access to treatment (Karam *et al*. 2006), a figure that has possibly worsened since the refugee crisis. Smartphone use and Internet coverage in Lebanon are high, with an estimated 96% of people having a mobile phone subscription and 76% of people regularly using the Internet (International Telecommunications Union, 2017). A recent United Nations report estimates that Syrian refugee communities are also known to have high accessibility to smartphones and the Internet, at approximately 80% household usage (UNICEF *et al*. 2017).

The World Health Organization (WHO) has developed an Internet-delivered behavioural activation intervention to treat symptoms of depression among adults, called *Step-by-Step* (Carswell *et al*. 2018). The intervention consists of five approximately 30 min sessions that are delivered on a weekly basis over 8 weeks (to allow flexibility of pace for users). Step-by-Step predominantly uses psychoeducation, behavioural activation (including specifically a session on social support activation) and some simple relaxation techniques. The Step-by-Step sessions consist of a narrated story of a character who has learned how to better manage his/ her mood from their doctor and an interactive part where the user can plan his/her own activities for the week to come. This story can be watched via video of a slideshow of still images and a voice over, or read like a comic book where the user swipes to see the next illustration with the text beneath. A story was used as the vehicle to transmit the therapeutic content, as stories and storytelling were deemed to be globally and culturally universal and engaging from an anthropological perspective. The intervention includes audio-recorded breathing and grounding exercises that beneficiaries can listen to. The companion in the story is tailored according to the gender of the client, and users can choose between characters that may resonate with some of the cultural groups in Lebanon (e.g. woman with/without a headscarf or man with/without a beard). It is noteworthy that the story content is common to all genders in terms of symptoms expressed, with slight adaptations in the activities to enhance relevance to each gender. Beneficiaries are asked to apply the exercises and activities between the sessions. The intervention is supported by trained non-specialist assistants (called 'e-helpers') who have weekly phone or message-based contact with users to provide support and guidance, lasting around 15 min per week.

The WHO, the Ministry of Public Health (MoPH) in Lebanon and other project partners are currently testing the feasibility of using Step-by-Step in Lebanon in a pilot study. Following this initial pilot, Step-by-Step is being tested in a number of fully powered randomised controlled trials in Germany, Sweden, Egypt and in Lebanon, commencing in 2018. Step-by-Step had been written in a generic manner and with global usage in mind, but in order to use Step-by-Step in Lebanon, it was necessary to sensitively adapt the intervention to the culturally diverse local setting, considering

the three main population groups: Lebanese, Palestinians and Syrians.

Lebanon has a varied cultural landscape, owing to rich religious diversity, a complex colonial and migration history and a highly politicised post-conflict environment. A systematic review identified 22 studies on the use of Western-developed interventions in the Middle East. In this review, cultural incompatibility accounted for the majority (54%) of barriers to implementation. Further barriers were lack of public awareness around mental health; gender-related norms; stigma and diminished social status of people with mental health problems; and language and presentation of distress (Gearing *et al*. 2013). This review shows that when delivering psychological interventions in Lebanon that are based on Western concepts of mental disorders, cultural adaptation is needed.

Cultural and contextual adaptation is an important step of formative work in delivering a pre-existing mental health intervention to culturally divergent client groups (Heim *et al*. in press) in potentially diverse settings. Several studies showed that adapted interventions have high effect sizes and that adapting psychological interventions to the local culture can increase their effectiveness (Hall *et al*. 2016). Two meta-analyses found higher effect sizes of adapted interventions than non-adapted ones (Griner & Smith, 2006; Benish *et al*. 2011). One additional meta-synthesis that included studies testing depression treatments in non-Western populations found high effect sizes [standardised mean difference (SMD) of −0.72] for adapted interventions compared with their various control conditions (but not compared with the same unadapted intervention) (Chowdhary *et al*. 2014). Finally, one study compared effect sizes of self-help or minimally guided interventions (i.e. books or online interventions with approximately 15 min of personal guidance per week) that were used cross-culturally. The authors found a high pooled effect size of adapted interventions (SMD = 0.81) and that the efficacy of the intervention increased with a point increase in the *extent* of cultural adaptation (Harper Shehadeh *et al*. 2016) showing a dose–response effect. On the other hand, in a recent meta-analysis of studies testing psychological interventions for the treatment of depression in low- and middle-income countries, cultural adaption did not affect effect sizes (Cuijpers *et al*. 2018). To what extent and what kind of cultural adaptation is important is still subject of current research.

One shortcoming in cultural adaptation research is that adaptation methods are not often described in detail by authors, with two of the above meta- analyses citing incompleteness (within publications) or difficulty in attaining information on cultural adaptation methods (Chowdhary *et al*. 2014; Harper Shehadeh *et al*. 2016). This highlights a need for research teams or intervention implementers to publish their methods of adaptation and report adaptations in a concise way.

Some common elements of methods used across studies that cite adaptation methods include ensuring that cultural adaptation should be ecologically valid and informed by research with stakeholders, use flexible methods with the aim of improving engagement, be acceptable and relevant while maintaining a balance of fidelity to the original intervention, and have a cultural fit (Saez-Santiago *et al*. 2017). It is important to document adaptations as well as the reasons for them (Bernal & Rodriguez, 2012). For systematic documentation and dissemination of methods, it is necessary to conceptualise and report the adaptations that have been made, which can be complex

when considering the abstract nature of cultural needs and specificities.

The aim of this article is to share experiences and methods that were used during the contextual adaptation of the Step-by-Step e-mental health behavioural intervention. Hwang (2006) stresses the importance of using bottom-up processes in cultural adaptation, i.e. involving community members and key informants when developing culture-specific interventions, as opposed to top-down cultural adaptations of an existing unadapted treatment developed for other groups. This view parallels the distinction between etic and emic research in mental health. The etic perspective assumes that diagnostic categories of mental disorders and corresponding treatments are universally applicable, whereas emic approaches address cultural concepts of distress and recommend using cultural-specific treatments and outcome measures (Kohrt et al. 2014). We opted for a careful balance between these two approaches: Step-by-Step is based on evidence-based techniques and designed by the WHO, thus developed primarily top-down, but the process of cultural adaptation was based on a bottom-up approach, as described below.

Methods

Content preparation

The content of Step-by-Step was first written in simple English to maximise its adaptability and to ensure that people with primary school level education would be able to access the content. This was then translated into classical Arabic by a professional translator. Given the intervention is a narrative story, to make the intervention more engaging and relatable, the project partners decided to translate the story into a spoken dialect of Arabic. The translation brief was that it would be representative of the three main dialectic groups in Lebanon: Lebanese, Syrian and Palestinian. The dialect translation was carried out from the classical Arabic translation by the project coordinator (JAR) with the assistance of other local staff (EZ and WK). This translation was then reviewed by one Palestinian, Lebanese and Syrian acquaintance (lay persons) of the project staff who were not familiar with the project. Small changes were made post-review, and then reviewed by a mental health professional to ensure that the original meaning and therapeutic aspect had not been lost throughout the adaptation.

Selection of participants

Participants were first approached by the front-line workers in the primary health care centres (PHCCs) and they provided their consent to be contacted by the research team. The qualitative work consisted of 11 key informant interviews (KIIs) and eight focus group discussions (FGDs) with several target groups recruited through four PHCCs across Lebanon so as to represent different cultures and population groups. Stakeholders ranged from mental health professionals, PHCCs managers and front-line workers who could provide insight based on their familiarity with community presentations of and beliefs around depression and community health-seeking behaviours. Moreover, people from the community (Syrian, Palestinian and Lebanese men and women) took part in the cognitive interviewing as well as detailed in Figure 1. Table 1 in Appendix 1 details the recruitment of participants.

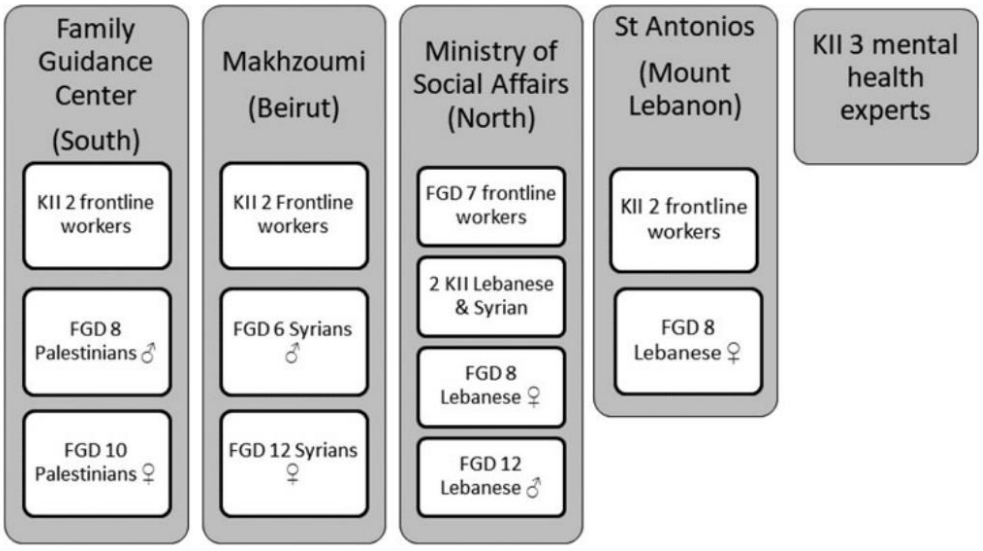

Figure 1. Diagram showing the distribution and number of key informant interviews (KIIs) and Focus group discussions (FGDs) across primary health centres (PHCCs). (NB: all Kiis and FGDs took place in PHCCs except for the KIIs with mental health experts that were held in private clinic settings.

Data collection

Most of the data collection was undertaken in January 2017 by the project coordinator (JAR) along with two research assistants that were independent from the research project. The project coordinator contacted participants by phone and took oral consent for participation and scheduled the date for the interview or FGD. The FGDs and KIIs for testing Step-by-Step content were semi-structured and their approach borrowed from the 'verbal probing' technique used in cognitive interviewing (Drennan, 2003; Willis & Artino, 2013). Cognitive interviewing is a technique predominantly used for questionnaire design that asks respondents to think out loud as they go through a survey or questionnaire while using probing techniques with the aim of improving the clarity and utility of questionnaire items and ensuring they fulfil their purpose. KIIs lasted 1 hour and a half while the FGDs lasted 2 hours on average. A sample of the interview guide and adaptation form can be found in Appendix 2.

The cognitive interviewing sessions aimed at testing the story content (the illustrations and story were shown on a screen while research assistants read through the story text), audio relaxation exercises (which were played through speakers), and general acceptability and feasibility of the intervention (via discussion). Hence, sessions were divided into four sections: Introduction, idea of Step-by-Step and implementation; Step-by-Step story; Behavioural activation activities; other illustrations and audio. The four sections are detailed in Fig. 2. The KIIs and FGDs adopted the same structure below; however, KIIs with community members (post-FGDs) were more focused on specific sections or questions to clarify any controversial or unclear feedback that was given in the FGDs.

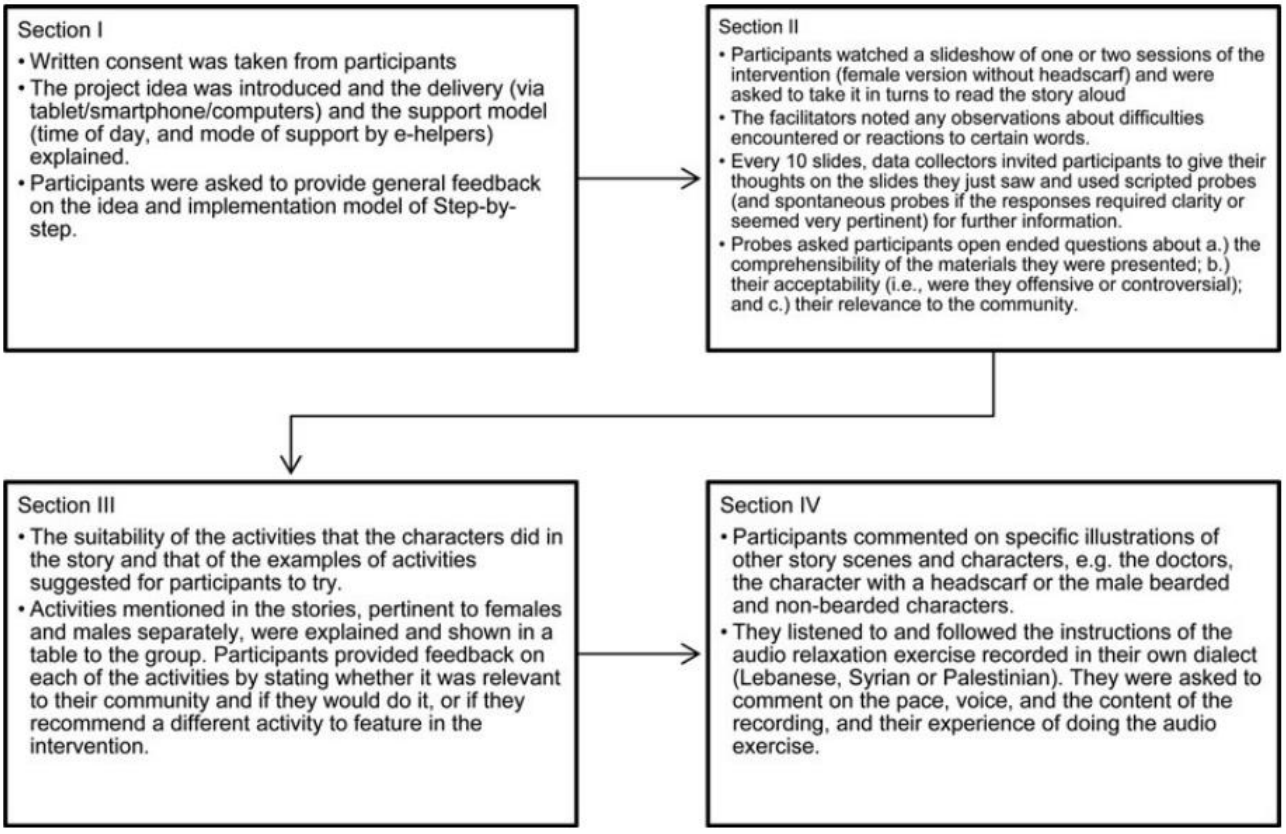

Figure 2. Chart showing the steps and content of the different sections of the cognitive interviewing.

Data analysis

JAR and a research assistant took detailed notes during each session. Suggestions for changing the intervention were recorded by the data collectors on a tracking sheet (original text, proposed change and its justification). Notes were translated into English and certain expressions used in Arabic were kept as they are alongside their corresponding English translation. Within each section of the KII or FGD, information was grouped into themes and subthemes that portrayed similarities and disagreements in opinions in a thematic analysis.

The results of the KIIs and FGDs were organized into tables by JAR and cross-checked by the other two data collection assistants. The results were presented in a 2-day adaptation workshop, attended by nine representatives of the project partners. This included local and headquarters WHO staff, National Mental Health Programme staff from the MoPH, experienced NGO representatives and a local mental health and psychosocial care consultant (who were either internationals or Lebanese nationals).

In this workshop, the final decisions as to what con- tent to adapt were made and documented and were informed by the feedback collected from the cognitive interviewing. The team took into consideration feasibility, cost and relevance when deciding on each change recommended, and after in-depth discussions, decisions were made following the majority votes. Following the

workshop, amendments to the English and Arabic content and to research procedures were made and reviewed by several team members.

Results

Results have been arranged according to the themes emerged in the four sections of cognitive interviews (introduction, idea and implementation, Step-by-Step story, behavioural activation activities, illustrations and audios).

Receptivity/relevance of Step-by-Step

Receptivity

Most participants stated that they would use the intervention because it (i) reduces the financial and physical barriers to care, (ii) reduces the stigma attached to the use of conventional care, (iii) makes them curious to know what happens next in the story, (iv) would teach them new techniques:

*We were interested in the session, we learned something new. When we start, we will be curious to continue, just like when you are watching a video, you want to watch it all and know how you will bene*fit. (Syrian Woman)

Non-receptivity

Some of the men across Lebanese, Syrian and Palestinian groups, 2/3 experts and 9/13 front-line workers were concerned that people would not use the intervention because (i) of the lack of awareness of the seriousness of mental distress, (ii) lack of awareness of the benefits of interventions that do not offer financial or material support, and (iii) because they have competing priorities, e.g. their basic survival needs, or are very busy.

[*I suggest to*] *Provide awareness* [*about Step-by-Step*], *and mention the word* '*medical intervention*' *to attract people*. (Front-line worker)

Relevance

Consensus was reached among all types of participants across genders and ethnicities, that this intervention is relevant, beneficial and essential to this society because of many prevalent socio-economic and political factors (financial problems, unemployment, marital problems, health issues, war, etc.). Step-by-Step was observed as a relaxing self-care tool, an empowering and educative platform, and the MoPH as a necessary and credible source of information.

Understandability and perception of depression

Participants' responses on what constitutes depression varied significantly. Some mentioned that depression is an illness, while others referred to it as a simple feeling of unease and even a personal decision. To some, it could be inherited, or caused by external factors and specific problems in a person's life like the wife's behaviour, or problems at work or home. Stigma around mental health was common. One statement was noted:

When you hear the word psychiatrist, it is associated with craziness or something. (Syrian Man)

Content

In this section, participants were asked to discuss the relevance, acceptability and clarity of the content, i.e. the storyline, characters, symptoms and presentation of distress, activity examples, illustrations and audio content.

Storyline

Most participants generally accepted the storyline; however, most recommended to emphasise solutions and write them into structured points. Some experts recommended to have an outline in the beginning of each session and add subsections and titles to make the sessions more structured and organised. Clarity and the level of understanding of the content were assessed by asking users to summarize the slides regularly. Consequently, many misconceptions were depicted, for instance, some were concerned that having a headache or shoulder pain meant that they had depression, while others thought that the hot drinks mentioned in the story such as coffee or tea were a treatment for depression. A major observation was that most people, even the more literate ones, were not at ease with reading the story, hence, they proposed to have an option of recording the story as a video to watch so that it captures people's attention and is easier to follow.

Characters

The profile of the character in the version of the story that was shown in cognitive interviewing portrayed a homemaker with children and house duties. She was relatable to some women, but not to working women or people with no spouse or children, who felt that they were not the target of this intervention. Some even warned that the extra focus on children in the story may revive feelings of sadness among the mothers who lost their children back in the war in Syria. The use of a doctor as the wise character who provides the advice or suggestions for improving one's mood was widely accepted, as the doctor is a very respected figure in the cultures approached and as a general health professional is not stigmatising. They stated that the doctor should be prescriptive and direct in the advice and suggestions s/he makes for getting better. By contrast, the companion should not be prescriptive, but instead provide only the story of how they used instructions that the doctor gave and to encourage the user to do the same thing.

With regard to disclosure about one's feelings, participants reported that spouses did not talk to each other about their feelings, rather they resorted to their best friends or siblings first, because of lack of understanding, prejudice or fear of abandonment (particularly in the case of Syrian women) or fear of showing weakness (mainly men).

If I tell my husband I'm depressed, he might think I'm of no use and go marry someone else. (Syrian, Female)

Symptoms and presentation of distress

The story does not use medicalising or clinical terms such as 'depression' or 'mental illness', but rather words like 'distress'. The participants accepted the use of the local idiom of distress 'تعبانة نفسيتي', or 'tired psyche' in English, which the team had used in the translated version; however, the symptoms of the mood problem needed revision. The first, unadapted version of the story used the

term 'tired cycle' to explain the vicious cycle between low mood, avolition and inactivity, which leads to even lower mood. However, FGDs showed that continuous lethargy, increased sleep and crying were not deemed relevant to men, who considered them to be exaggerated and indicative of total hopelessness. Participants in general noted that depressed people in Lebanon maintained their necessary activities and still went to work, yet, they were described to become irritable, tired, sad, frustrated or angry while continuing to function.

This is hopelessness. But humans shouldn't reach this level of hopelessness. It is an extreme case. (Palestinian Male)

People in Lebanon keep doing everything but they feel very sad and angry; so they need to stop and relax instead of staying active. (Expert)

They identified that people with mood problems experienced lifestyle change in that they stopped doing enjoyable activities and withdrew from their surroundings and social situations. This impression was supported by the experts who thought the story was unrepresentative of many presentations in Lebanon and should be toned down to respond to a wider scope of mild-to-moderate depression or higher functioning.

In Lebanon, people tend to have severe anxiety and usually say: I'm angry, I'm furious, I'm sad, I'm bored, I'm scared rather than I'm helpless, I'm tired, I'm miserable; they keep active but are anxious. (Expert)

Additional recommendations about the context and local understanding of mood problems were raised by the participants of the different nationalities. They suggested to add financial problems, stressful work conditions and violence as prominent community problems that might lead to people being depressed.

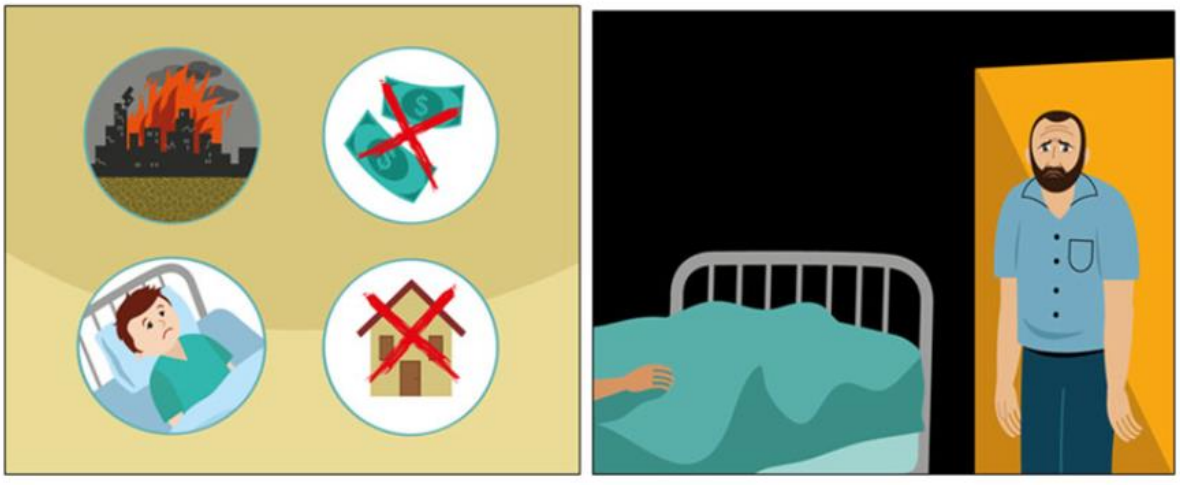

Figure 3. Example illustrations of distressing situations (images reproduced with permission from WHO).

Recommendations were also given at the level of the text whereby participants suggested different wording translations and metaphors that would appeal better and depict distress and recovery. For instance, the translation of mood in Arabic has some negative connotations, 'psyche' would be a better fit. Also, 'I could feel the sunshine again' was not commonly said in Lebanon, so was replaced by 'I felt lightness again'; the term 'satisfaction' in Arabic had sexual connotations to some religious groups so it was replaced by 'feeling of joy or peace'.

Illustrations and audio exercises

The study team was very aware of the heterogeneity of populations across Lebanon and globally who may use this intervention (e.g. nationals and refugees, high or low social economic status). In the illustrations brief, it was important to specify that illustrations should not include cues targeting one group over another as possible. For example, for depicting adversity and distress, the distressing situation is left interpretable (see Fig. 3).

All participants accepted the illustrations but suggested amendments to the facial expressions of the characters in the story to make them more realistic.

One comment concerned a particular hand gesture of the main character, along with the background colour (bright orange). Participants stated that the gesture in combination with the colour referred to a certain political sign and colour used by a Lebanese political party (see Fig. 4).

As for the audio exercises, people liked them and felt they were relaxing.

The audio is calming and gives people oxygen. (Lebanese men)

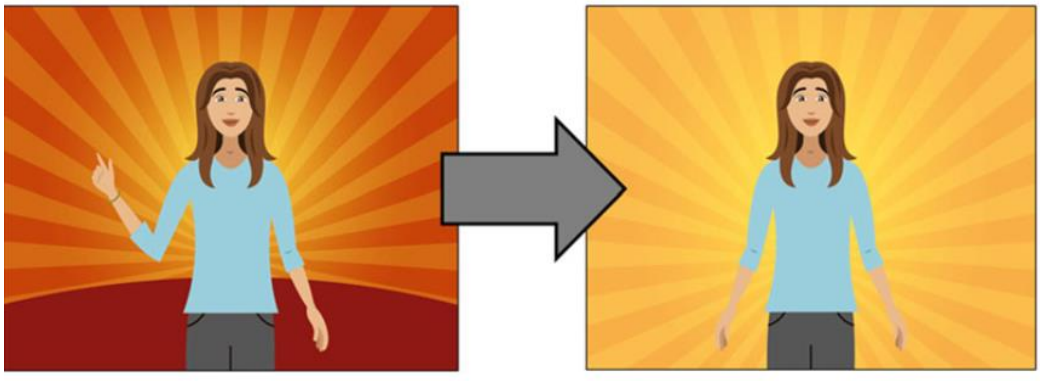

Figure 4. Example of how the colours and hand gesture were changed after adaptation. (Images reproduced with permission from WHO).

Activities

As part of the behavioural activation component of the intervention, activities are suggested with the main character in the story carrying out activities that will improve his or her mood. Gender specialists at the WHO reviewed the story and highlighted areas where activities were particularly gendered, e.g.

women only playing with children, males being angry and women crying, illustrating women in a submissive position compared with the husband, having the male character go out to play backgammon and the woman be indoors all the time. Some changes were made in reaction to this review (e.g. husband helping with preparing food or also playing with children, or both stories referring to anger and crying) and the team tried to have the same activity for both versions of the story wherever possible. However, the local team and participants of FGDs highlighted that gendered activities listed above were the reality in Lebanon and that the story should remain realistic to local norms for people to be able to relate to it. The final story was seen to broadly achieve a balance between removing unhelpful gender stereotypes while remaining realistic to the local situation.

Community participants, as well as health professionals recommended to start with the enjoyable self- care activities first, before doing necessary life activities, which are sometimes a stress factor for people in their community. They also highlighted the fact that people living in Lebanon needed to stop and pause for a while, and think about themselves. Most participants embraced the idea of encouraging people to gain social support and take some rest without feeling guilty about it as being very busy was very often discussed (see Fig. 5).

It's good to encourage women to gain support from their mothers/ relatives and take some rest without feeling guilty. (Expert)

Participants reviewed the story and a table of activities and commented on each of them. Strong opinions were held in support or against certain activities. An important point was highlighted by the Syrian women and men, who clarified that most Syrian women did not enjoy a high level of independence to go out of their houses alone, thus the example of the woman going out for a walk alone was not perceived as feasible to them. Participants suggested simple indoor self-care activities in sessions 1 and 2, like changing one's appearance and clothes from time to time, personal hygiene, praying, gardening for both genders, reorganizing or tidying the house for women, playing football or exercising for men. Outdoor more complex activities suggestions included going out with friends, spending time in nature, shopping, exercising, fishing, swimming, organizing a family trip, etc. A renowned topic for addition in all FGDs was that religion was an important component in people's lives and could be added as a solution to help against distress. Table 2 in Appendix 3 has examples of how activities were changed after cognitive interviewing.

You should stress a lot on religion and advice people to listen to prayers, talk about the importance of faith across all religions, faith gives strength. (Lebanese Women)

The examples below show how illustrations were changed based on the feedback generated, whereas other aspects of the intervention that were changed, are shown in Table 3 in Appendix 4.

Implementation of Step-by-Step

In this section, participants were asked to discuss the feasibility of Step-by-Step delivered via technology; thus, the feasibility, the length of sessions, the pace of the intervention, the setting

preferences, privacy concerns and the support methods were discussed.

Feasibility of technologized intervention

Despite the perceived relevance of the intervention, the feasibility of delivering Step-by-Step via e-platform was debatable. When asked whether it would be practical to use the intervention, answers varied among the different groups. Participants across different ethnic groups, mostly Palestinians and Lebanese, a minority among Syrians and 4/13 of the front-line workers believed that the intervention was feasible for many reasons, among which, user friendliness seemed to be an important factor. Also, the wide availability of mobile phones and Internet coverage in all households, even the most vulnerable ones, and the time and place flexibility associated with it, were considered as encouraging factors. Nevertheless, all Lebanese men noted that despite the friendliness of such an intervention and its flexibility, the slow and low quality of Internet connection might be a huge challenge for usage of such an intervention, whereas the majority of Lebanese women were more concerned about their very busy lifestyle and the length of sessions. A big proportion of the Syrian women and men had different concerns though; they mentioned that the main barrier for using an e-intervention was their illiteracy or electronic device illiteracy (especially older adults), and the majority of Syrian women stressed the fact that they did not have access to a phone most of the time as it is shared with their husband. These factors were also foreseen by the majority of the front-line workers.

if the internet speed is low, we would get angry and delete the app. (Lebanese, Male)

Length of sessions

With few exceptions, most participants had the impression that the sessions were too long and repetitive, and that there was more focus on symptoms and unnecessary details of the story rather than on solutions.

I prefer the session to last for 5 mins or 10 mins, not more than that. (Syrian, Male)

Pace

Some participants expressed that users might need more than a week to transition from one session to another and might need reminders to complete the sessions.

It's very difficult to get out of the sad phase in 1 or 2 weeks, this needs more time. (Syrian, Female)

Setting preferences

Preferred place of usage (e.g. at home, in public place) and time (e.g. after work) depended on gender and whether participants were homeworkers or worked outside. Most participants preferred to use Step-by- Step on their own phones instead of using tablets provided in the PHCCs for

convenience and privacy and due to lack of time.

I don't have time to come to the center to user it, especially that I can use it on my phone at home, on my convenience. (Lebanese, Female)

Accessibility, privacy and security

Lebanese and Palestinian participants reported that they did not have any problem using Step-by- Step and providing their contact information, while Syrian men and women and some Lebanese participants in the North area were more skeptical about it and declared that they might put fake numbers as they feared being spied on by certain agencies. Participants recommended the project to be disseminated through the local PHCCs because they are trusted, and to put the MoPH logo so that it adds credibility to the intervention. This is reflected in the following statement:
Some people might not like to enter their number, especially that there is an unknown organization involved and our information would be stored there. We would trust the MoPH better. (Lebanese women in the North)

E-helper support

When asked about the e-helper support, participants preferred to get an introductory call instead of an email, to get a notification before the call from the e-helper, and to get the number of the e-helper who would call them in advance. This finding was stressed particularly when phones were shared with spouses (mainly for Syrians). Male and female participants reported being less desirable husbands or wives if their partner should find out they had emotional problems. But trying to keep the identity of the caller from their partner could raise questions about their fidelity and even put them at risk of gender-based violence. Syrians preferred to get phone calls and talk to the e-helper, while some of the Lebanese preferred messages only.

Discussion

Through carrying out in-depth cognitive interviewing with community members, mental health professionals and front-line primary health care staff, valuable information about the content, implementation and the prospective use of the WHO Step-by-Step programme was gathered and used to adapt the intervention to enhance cultural acceptability among different groups in Lebanon.

The methods used for the adaptation of Step-by-Step are not dissimilar to other methods used for gathering data to inform adaptation of psychological interventions in low- and middle-income countries. In a paper providing an overview of the procedures adopted by three such studies, the wider Step-by-Step project some-what parallels the methods of these research teams in drawing upon the UK Medical Research Council framework for the design and development of complex interventions (Patel *et al*. 2011; Craig *et al*. 2013). This is by using a multi-phase approach (exploratory or formative work on context, feasibility and piloting with process evaluation before definitive testing), of which this study entails part of the first phase. We have used a systematic and documented approach to gathering data for adapting the intervention, engaging a broad range of stakeholders including health workers and community members and previous to this research phase,

a number of Lebanese mental health service providers and public mental health academics for their inputs on intervention development and project planning (Patel *et al*. 2011).

During the adaptation workshop based on the qualitative data, the team made decisions about what characteristics and content to revise while maintaining the fidelity of the intervention. Adaptations led to the intervention being approximately 30% shorter, some illustrations being re-drawn or created, and many other content changes and methodological considerations taken into account. One very important adaptation referred to how symptoms of depression were explained in the intervention. The original term 'tired cycle' was changed into 'sadness and withdrawal cycle', and the symptoms were changed from avolition and inactivity to maintaining daily activities but with low mood, irritation and anxiety (see figure 5). From our results, we cannot conclude whether this presentation of symptoms corresponds to an emic cultural concept of distress (Kohrt *et al*. 2014). It may also be that due to the low socio-economic status of many people in a middle-income country such as Lebanon, inactivity is not an option because people have to secure their livelihoods. Ethnographic research on cultural concepts of distress would be required to better understand this concept.

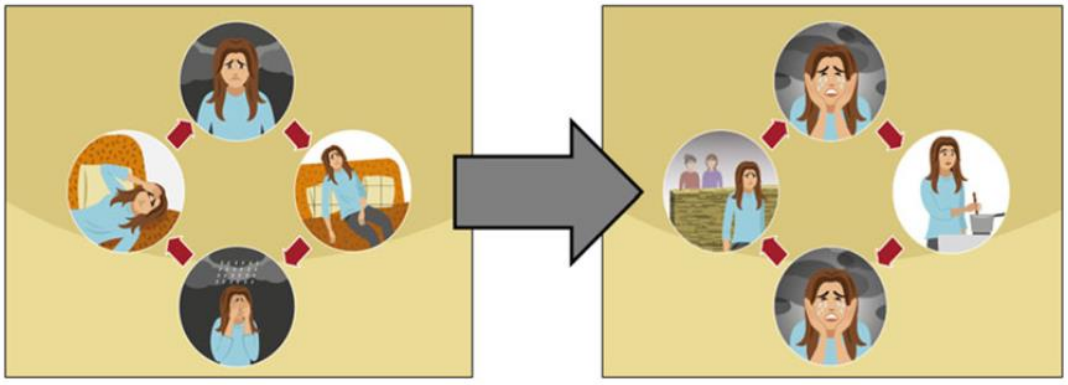

Figure 5. Example of how the 'tired cycle' was changed to the 'sadness and withdrawal cycle' after adaptation. The new version shows the main character not in a state of inactivity, but continuing with normal activities but in a depressed mood. (Images reproduced with permission from WHO.)

Similarly to the content, decisions pertaining to the delivery method of Step-by-Step were made and are detailed in Table 3 of Appendix 4. Given the range of views on acceptability of the support element of Step-by-Step, one main decision was to give the choice to the participants to choose their preferred method of contact (phone, email, chat), their preferred day and time. This is to prevent any breach of privacy, confidentiality and any intrusiveness of the support.

We did not find a preference for traditional methods of healing as some studies suggest: (Karam *et al*. 2006; Gearing *et al*. 2013) among the cognitive interviewing participants though this is likely because we recruited participants through mainstream medical services. However, our findings parallel results from a systematic review which identified a preference for directive and authoritarian

approaches to care, mirrored in our focus groups by the preference of a doctor figure who is prescriptive and directive (Gearing *et al*. 2013). Our findings also dovetail with the barriers identified in this systematic review, such as lack of awareness around mental health, gender issues and stigmatization of people with mental health problems.

Strengths and limitations

Using community members from the cultural group one is adapting to, as was done for this adaptation, is said to be the best way to arrive at the most contextually appropriate revisions of psychological interventions (Hall *et al*. 2016). A recent and large meta-analysis found that most cultural adaptation methodologies take a top-down methodology to adapt interventions, with just four out of 78 studies adapted interventions using a bottom-up, or community-driven approach (Hall *et al*. 2016). A strength of the present study is that it adds to the literature in a context of a lack of published accounts of bottom-up cultural adaptation practices in the region. Furthermore, we ensured that the three main cultural groups in Lebanon were involved, that is Lebanese, Syrian and Palestinian men and women.

This cognitive interviewing had several limitations. First, we recruited participants through primary health care services, which may have biased our results towards opinions that are compatible with medical health care seeking (and therefore not including people more inclined to seek traditional forms of care). Second, the final decision makers as to adaptations did not include Palestinians nor Syrians. Third, though we did engage target community members, for ethical reasons, we did not use target community members who had common mental disorders, so we could have gone one step further with our ecological validity. We did how- ever try to include the local mental health perspective by getting feedback from local mental health experts and from PHCC staff.

Implications and future research

In light of limited evidence on methods of cultural adaptation in current literature, this paper provides a detailed report on methods and results of a bottom-up, cultural adaptation process of an evidence-based online intervention for the treatment of depressive symptoms in Lebanon.

Hopefully, this will encourage other researchers and implementers to use bottom-up approaches to adaptation and report on their experiences. So far, evidence on the importance of cultural adaptation is mixed, with some meta-analyses showing a higher efficacy of adapted interventions compared with non-adapted ones (Benish *et al*. 2011; Hall *et al*. 2016), whereas one more recent meta-analysis found no effect (Cuijpers *et al*. 2018). Future research will show whether cultural adaptation such as implemented in the present study increases the usability and effectiveness of interventions. But regardless of these very important aspects, we are convinced that using culturally specific illustrations and examples, and making sure the content is meaningful and non-offensive, should be a minimal standard when delivering interventions to culturally diverse groups.

Conclusion

Bottom-up cognitive interviewing with community members, front-line health workers and mental health professionals provided very relevant information which will hopefully contribute to increase the relevance and acceptability of the Step-by-Step intervention. It was important to have community members involved in informing decision-making and have experts ensure that final decisions of what changes to make to the intervention would maintain fidelity of the intervention post-adaptation.

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Ethical standards

The authors assert that to their knowledge, procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008. To see the consent form we used, please see Appendix 5.

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Appendix 1

Table A1 Shows the steps and criteria for participant selection for the cognitive interviewing.

Recruitment of participants	Centres were selected based on the availability of mental health services, on their participation in the National Mental Health Programme activities, and on typical patients' demographics (Lebanese, or Syrian or Palestinian nationalities) In total, three mental health professionals and 13 PHCC front-line workers were interviewed, 64 community members including Lebanese, Syrian and Palestinian nationalities participated in FGDs, and two community members were interviewed individually for more in-depth information PHCCS helped recruit participants from among their beneficiaries for the FGDs by approaching them while in the waiting room. Two front-line workers were interviewed from each centre and one or two FGDs took place in each centre for women (*n* = 38) and men separately (*n* = 26) People of these three nationalities, above 18 years of age, and with primary school level literacy (in order to be able to engage with the Step-by-Step materials) were included in the study The focus group participants were not screened for depression. Participants completed a written consent form with the assistance of the data collector where necessary and were remunerated US$15 for their time

Appendix 2

Interview questions and example adaptation monitoring form – Mental Health Experts/Front-line personnel

Date of interview:

Population with which the interviewee works: (Lebanese, Palestinian, Syrian)

Area of Lebanon in which the interviewee works: Year of experience in mental health:
Sex of interviewee:

Thank you for being willing to provide feedback on this e-Mental Health intervention for populations living in adversity. We will be showing you segments of the intervention. At various points, we will stop to ask you questions about its relevance and acceptability. If you notice something prior to the point at which we stop, please call out and we will stop immediately. As you listen and read, please ask yourself the following questions:

- Does the content make sense for – or is it relevant to – Lebanese nationals and Syrian or Palestinian refugees?
-
- Is the content appropriate for the target population? i.e., is it meaningful, understandable and not offensive or upsetting? How could we change the content or the visuals or any other aspects of the intervention to make it more relevant and acceptable?

Please keep in mind that you are seeing one version of the story. There will be several other versions with different characters (show the different characters).

Participants can choose which character to watch. The story you will watch is also the female version. There will be a male version with different activities but the same strategies.
Can we begin?

Stage of adaptation	Original text including document name and page number	Proposed change	Justification to change original text	Notes	Change agreed
Contextual research			☐ Not understandable ☐ Inappropriate ☐ Irrelevant ☐ Other		☐ Yes ☐ No
Contextual research			☐ Not understandable ☐ Inappropriate ☐ Irrelevant ☐ Other		☐ Yes ☐ No

Appendix 3

Table A2 Shows some examples of original story activity suggestions alongside suggestions from partipants to make amendments.

Original activity or activity suggestion	Participant feedback and suggestion for amendment	Decision made during the adaptation workshop
Making and drinking a cup of tea (Both genders)	Drinking tea was a simple, pleasant and common activity, yet, to be replaced by 'drinking a hot drink' which could be coffee, tea or matté in the case of a certain population in Lebanon, to avoid misleading people into believing that tea had herbal or therapeutic effects against depression	Change to drinking a hot drink and reduce the frequency that this activity features in the story
Going for a walk (Both genders)	Walking was deemed to be very beneficial; yet, instead of walking alone, walking with company could be an option for some Syrian women who cannot go outside unaccompanied	Walking was maintained as a very healthy activity. In some of the illustrations, the character is walking with family of friends but text does not specify alone or in company
Reading a book (Both genders)	Reading a book was thought to be too complicated and stressful for depressed people. Also, it does not seem to be very common among adults and might be offensive to people with low literacy	This activity was removed
Playing with one's children (Both genders)	Playing with one's children was thought to be a stressful activity that adds burden to a depressed person. It was advised by the participants and the experts to postpone this activity in the story from session 1 to session 4 or 5	Overall, the references to children were reduced, men were included in illustrations with the children and this activity was included for both men and women
Listening to favourite singer (Both genders)	Listening to favourite singer was criticized by some religious people who noted that listening to music was prohibited in their religion. Participants suggested that it could be kept as an option 'listen to music' and music could be classical	This was changed to listening to favourite music
Going to the market first alone then with the children (Both genders)	Taking the kids to the market could be very stressful and difficult to a depressed person and even embarrassing in case that person is from a low socio-economic class. The suggestion was to replace it with going to the market alone and remove going with children or postpone it to session 4 or 5	This was changed to taking the family out for the day, with a practice outing of getting picnic supplies from the market alone
Inviting, preparing and hosting a family dinner (Females only)	Invite family to come over for dinner is good and enjoyable but costly and impractical for some Syrians since several families live in the same apartment. Thus, making dinner and or dessert could be a better alternative	This was maintained for women as a complex social activity but with four extra people (rather than saying 'extended family')
Going to meet friends to play chess at a café (Males only)	Meeting a friend to play chess in a café was considered relevant and applicable, yet better replace chess with cards or backgammon which are much more common in this culture. Also, encourage men to spend time with their families at home as well	This was replaced with going to the cafe or a friend's house to play backgammon

Appendix 4

Table A3 shows the changes pertaining to the different aspects of the content and delivery method of the intervention.

Topic	Decisions based on results from FGDs and KIIs
Length of sessions	The project team took on board the advice from many participants of summarising the story into more concise sessions by reducing redundancies and removing unnecessary details of the story (approximately two-thirds of its original length)
Pace of intervention	The time gap between the sessions was extended, users are given 10 days to complete one session before sending a reminder to start the next
Support time and method	Project team took into consideration the time preferences of the community and increased the flexibility of the support methods by providing more options (phone, email or chat support)
Role of characters	Participants suggested that the doctor and narrator should have different roles to add credibility to the advice. Therefore, a prescriptive role was given to the doctor, and narrative role to the main character
Inclusiveness	Based on the comments from single and working female participants who had difficulties in seeing themselves related to the narrator, the project team decided to include less illustrations of and reference to children in the story and is considering making a version of the story for single users
Clarity of the content	The team responded to the comments related to the misconceptions of the therapeutic examples used, and the difficulty of reading the story. The story was made into a video and the psychoeducational parts were reformulated
Concept of depression	A central part of the story, the 'tired cycle' was updated to the 'sadness and withdrawal cycle' in response to participants' suggestions. See Fig. 3 for an example of how this element of the story changed
Illustrations	One illustration was changed with regard to colour and hand gesture because the original referred to a political party in Lebanon (see Fig. 4)

Appendix 5

Focus Group Discussions with Potential Users Consent form
Ministry of Public Health in Lebanon

My name is ----------. I am working with the Ministry of Public Health in Lebanon on a research project conducted by the World Health Organization with the Ministry of Public Health in Lebanon, and supported by a charitable foundation in Switzerland, Fondation d'Harcourt. I am inviting you to participate in a focus group discussion in order to give us in-depth feedback on the content of an internet-based mental health program. This program is called 'Khoutweh Khoutweh'.

Before we begin, I would like to take a few minutes to explain why I am inviting you to participate and what will be done with the information you provide. Please stop me at any time if you have questions about the focus group. After I've told you a bit more about the project, you can decide whether or not you would like to participate.

'Khoutweh Khoutweh' is a minimally guided, electronic self-help program aimed at addressing the mental health needs of Lebanese nationals and Palestinian and Syrian refugees living in situations of adversity in Lebanon and experiencing difficult emotions. This intervention will eventually be used in selected primary health centres in Lebanon. Before using this intervention, we want to make sure that it is relevant, and that the content is easy to understand and accept- able. We are inviting you to participate in a focus group discussion to provide in-depth feedback on whether the content of the intervention is understand- able, acceptable, and relevant. You have been selected from the beneficiaries of this primary health centre/ non-governmental organization to participate in the research. The interview will take a maximum of 3 hours. Approximately 10 other participants will also be asked to participate.

If you agree to participate, we will show you the content of the intervention and you will be asked to answer several questions along with a group of other participants. Questions will address the relevance and acceptability of the translated and adapted text, audio scripts and illustrations to your culture. Your participation is entirely voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty. If at any time and for any reason you would prefer not to answer any questions, please feel free to skip those questions. If at any time you would like to stop participating, please tell me. Your decision to withdraw will not involve any penalty or loss of benefits to which you are entitled. Discontinuing participation in no way affects your relationship with your health center, the non- governmental organization or any of the three partners that are implementing this program (Ministry of Public Health, the World Health Organization and Foundation d'Harcourt). No one from *insert name of NGO* will be present when we are conducting the focus group discussion with you.
Your participation in this focus group does not immediately involve any physical risk or emotional risk to you beyond the risks of daily life. that listening to the story might cause you some emo- There is a slight chance and you can choose to discontinue the interview or wait a while and then continue.

You receive no direct benefits from participating in this research; yet, you may learn some tips to

support your own mental health. Your participation does help to improve the program and inform the adaptation of an intervention that will have potential to promote mental health of persons living in adversity in Lebanon. Refreshments will be available; there are no financial benefits for participating in the discussion but we will provide LL10,000 for any transportation costs you might incur.

To secure the confidentiality of your responses, no identifiers will be kept. We will only note age, gender, nationality, and marital status to use for descriptive statistics. We will take handwritten notes without referring to your identity so that we accurately remember all the information you provide while preparing the project report. Hard copies will be stored in a locked cabinet in the office of the research. Soft copies will be saved on a password protected computer. Data access is limited to the Principal Investigator and staff working directly on this project. Records may be monitored by the IRB, but all information will remain confidential. All data will be destroyed responsibly after the required retention period (usually three years).

You will be provided a copy of the consent form. If you have any questions, feel free to ask them now.

You may also communicate now or in the future with the Principle Investigator responsible for the research: Dr. Rabih El Chammay Phone: +961 1 611 672 ext.: 125; E-mail: rchammay@moph.gov.lb

Are you interested in participating in the focus group?

o Yes o No

Consent to quote from the focus group:

I may wish to quote from this focus group either in presentations or in reports resulting from this work. A pseudonym will be used in order to protect your iden- tity. You can still participate in the interview even if you do not want us to use quotes.

Do you permit me to quote from this focus group?

o Yes

o No

Participant's name:

Date:

Signature:

Printed name of person obtaining consent:

Date

Signature of person obtaining consent:

Cultural Adaptation of a Scalable World Health Organization E-Mental Health Program for Overseas Filipino Workers

Abstract

Background:
Electronic mental (e-mental) health interventions can address mental health needs of different populations. Cultural adaptation of these interventions is crucial to establish a better fit with the cultural group and to achieve better treatment outcomes.

Objective:
This study aimed to describe the cultural adaptation of the World Health Organization's e-mental health program Step-by-Step for overseas Filipino workers. We used a framework which posits that cultural adaptation should enhance (1) relevance, wherein the cultural group can relate with the content; (2) acceptability, where the cultural group will not find any element offensive; (3) comprehensibility, where the program is understandable; and (4) completeness, wherein the adapted version covers the same concepts and constructs as the original program. We aimed to have English and Filipino and male and female versions.

Methods:
Overall, 3 experienced Filipino psychologists provided their perspectives on the program and how it might be adapted for overseas Filipino workers. We then adapted the program and obtained feedback from 28 overseas Filipino workers from diverse industries through focus group discussions. We conducted 7 and 9 focus group discussions with male and female participants, respectively. Per discussion, cognitive interviewing was used to probe for relevance, acceptability, comprehensibility, and completeness of illustrations and text. Participant feedback guided iterative program adaptations, which were again shown to participants for validation and improvement.

Results:
Several issues were raised by participants about the generic version of Step-by-Step. There were elements deemed irrelevant, like unfitting characters, lack of Filipino values, and unsuitable problems and activities. There were unacceptable components that were stigmatizing, political, inappropriate to context or subgroups, and too feminine for male users. Some elements were incomprehensible, unclear, or complicated. To address these issues, we made key adaptations. To enhance relevance, we adapted the narrative to match the experiences of overseas Filipino workers, incorporated Filipino values, and illustrated familiar problems and activities. To increase acceptability, our main characters were changed to wise elders rather than health professionals (reducing mental health and help-seeking stigma), political or unacceptable content was removed, and the program was made suitable for overseas Filipino workers from different sectors. To increase comprehension, we used English and Filipino languages, simplified the text to ease interpretation of abstract terms, and ensured that text and illustrations matched. We also used Taglish (ie, merged English and Filipino) when participants deemed pure Filipino translations sounded odd or incomprehensible. Finally, we retained the core elements and concepts included in the original Step-by-Step program to maintain completeness.

Conclusions:
This study showed the utility of a 4-point framework that focuses on acceptance, relevance, comprehensibility, and completeness in cultural adaptation. Moreover, we achieved a culturally appropriate adapted version of the Step-by-Step program for overseas Filipino workers. We discuss lessons learned in the process to guide future cultural adaptation projects of e-mental health interventions.

Introduction

Background

The use of technology to deliver mental health interventions proliferated in recent years, with electronic mental (e-mental) health interventions providing accessibility to needed mental health interventions [1,2] for more people [3] and at greater frequency [4]. The use of e-mental health interventions is especially promising for vulnerable and marginalized populations such as migrants. They help reduce the stigma associated with help-seeking and minimize treatment barriers such as geographical distance and culture, religion, and language differences between users and providers [2,5].

E-mental health interventions that undergo cultural adaptation are more effective. Cultural adaptation is "the systematic modification of an evidence-based treatment (EBT) or intervention protocol to consider language, culture, and context in such a way that is compatible with the client's cultural patterns, meanings, and values" [6]. Cultural adaptation is warranted when an intervention developed for one cultural group will be implemented within a different cultural group. When an intervention is adapted, a better fit between the program and the cultural group is expected, which in turn leads to better treatment outcomes [7].

Culturally adapted interventions are effective. A meta-analysis [8] of 78 studies revealed that culturally adapted face-to-face interventions performed better than the comparison conditions (another active intervention or no intervention), with an average effect size of *g*=.67. Furthermore, culturally adapted interventions are more effective than their original unadapted versions, with a medium effect size of *g*=.52. Another meta-analysis [9] of e-mental health interventions found that cultural adaptation resulted in a greater reduction in depression and anxiety symptoms. Essential elements for adaptation according to the Bernal and Saez-Santiago framework [10] include language, persons, metaphors, content, concepts, goals, methods, and context. Every additional element adapted resulted in a 14% increase in intervention efficacy.

It should be noted, however, that cultural adaptation does not equate with completely rewriting the program. In fact, a systematic review [11] on cultural adaptation of interventions for depressive disorders showed that all the studies included in the review preserved the original treatment's framework and core principles that were deemed acceptable. The adaptations were made to establish cultural relevance, improve treatment acceptability, and remove barriers to care (eg, lack of trained professionals and limited literacy). Inclusion of barriers to care could be considered as implementation rather than a cultural aspect and suggests that in some studies what counts as a cultural adaptation may be poorly defined.

Cultural adaptation involves an integration of top-down and bottom-up approaches [12]. The original program (top-down) is modified based on feedback from the intervention target population (bottom-up), that is, the original program is adapted based on input from the cultural group to be responsive

to the cultural group's context and specific mental health concerns [8].

The World Health Organization is developing several evidence-based interventions—including transdiagnostic programs—designed to be scaled up to reach populations globally that lack access to needed mental health services [13]. We adapted one of these, the Step-by-Step program, an e-mental health program based on the principles of behavioral activation treatment for depression, along with additional strategies such as psychoeducation, stress management, and help-seeking [14]. Following the internet- and mobile-based intervention categorization [1], Step-by-Step is considered a minimally guided self-help program, wherein a nonspecialist *eHelper* may provide technical support and assistance in accomplishing program activities through phone calls or text messaging for up to 20 min a week.

In places with more established services, Step-by-Step may be suitable for use within a stepped-care structure, where users who show mild-to-moderate levels of symptoms could be referred to higher-intensity services should they require it on completion of the program. The program contains text and stories with corresponding illustrations and 2 main characters. The first character is an expert who helps the second character by sharing behavioral techniques to overcome problems and by explaining the concepts behind the problems and the techniques offered in the program. The second character narrates their experience of using the Step-by-Step techniques to overcome depression, reporting their previous encounters with typical problems and psychological symptoms of the target population and explaining how they employed the program to reduce these problems.

The original version already has 3 of the 4 desired features of effective e-mental health interventions, as it is based on the empirically tested theory of behavioral activation, it is structured, and it is interactive or experiential [15]. The last desired feature of being targeted for a specific group [15] must be addressed through cultural adaptation. To ensure high-quality adaptation of Step-by-Step, we followed the approach used by Manson [16] and van Ommeren et al [17]. Manson [16] theorized that the end product needs to be (1) acceptable, with nothing in the program offensive or potentially offensive to the cultural group; (2) relevant, in that the program's content is related to the cultural group and does not contain unrelated phenomena; (3) comprehensive or understandable by the cultural group; and (4) complete, in that the program covers the same semantics, concepts, and theoretical constructs as the original version.

In this study, Step-by-Step was adapted for overseas Filipino workers (OFWs). There are 2.24 million OFWs around the world [18]. The majority (85%) work in Asian countries such as Saudi Arabia, United Arab Emirates, Qatar, Singapore, and China (ie, Macao and Hong Kong Special Administrative Regions, SARs). There are roughly the same number of male and female OFWs, but occupational differences exist between the groups. Male OFWs are mostly plant and machine operators and assemblers (24.7%) and craft and related trade workers (23.1%), whereas female OFWs are mostly employed as household service workers and cleaners and in other low-skilled occupations (56.2%). In Macao SAR of the People's Republic of China, OFWs are the second largest migrant group at 29,426 [19]; roughly half of them are household service workers, more commonly referred to as domestic workers, followed by hotel and restaurant workers.

Previous studies focused on the risks and challenges that OFWs and other labor migrants experience. OFWs' primary reason for working abroad is the desire to escape poverty or to achieve socioeconomic mobility, mainly for their family, rather than individual aspirations [20,21]. However, while abroad, and similar to other labor migrants, OFWs are at higher risk of experiencing mental health–related

issues such as loneliness, stress, anxiety, depression, and serious mental illness [21,22]. However, resolving these challenges is problematic as labor migrants tend to have poor access to mental health services [23-25] and poor support systems [26]. E-mental health interventions are a way to address their mental health needs as more than 90% are smartphone users, and there is high potential uptake as 68% are likely to use a Web-based program when one is available [27].

Objectives

This study aimed to culturally adapt the WHO Step-by-Step program for overseas Filipino labor migrants. We made English and Filipino and male and female versions. It was intended for use by OFWs engaged in different occupations.

Methods

Participants

There were 31 participants, all of whom were selected through purposive sampling. We used a 2-stage approach (refer to Figure 1), first interviewing 3 Filipino psychologists with considerable experience and expertise in psychological practice and in working with OFWs, using Zoom video conferencing (each approximately 120 min long). The second stage consisted of focus group discussions (FGDs) with 28 OFWs in Macao. Of the FGD participants, 16 were women, aged 24 to 52 years (mean 36.31, SD 9.44), and employed as domestic workers, caregivers, and food and beverage workers. In addition, 9 of them were married, 6 were single, and 1 was widowed. The length of time working in Macao ranged widely, from 1 month to 12 years (mean 4.28 years, SD 3.46). Furthermore, 12 participants were men, aged 23 to 47 years (mean 30.58, SD 7.66), and employed in hotel and casino, food and beverage, and facilities management industries. Half of them were single and half were married. They had been working in Macao for an average of 1.63 years (SD 1.12), with a range of 6 months to 4 years. FGDs were conducted separately for male and female participants, with each FGD covering 1 to 3 sessions of the program. Due to scheduling difficulties, participants were not able to join all FGDs to discuss all the sessions of the program. Each participant joined at least 1 FGD and at most 6 FGDs. There were 7 male and 9 female FGDs in all, with 2 to 11 participants per FGD. The FGDs lasted between 2 and 3.5 hours and were conducted in private rooms in a local nongovernmental organization (NGO) or in a university. The FGDs were held on Saturday nights and Sundays, either after participants' work or during their day off. The participants were remunerated MOP $100 or roughly US $12 per FGD.

Materials

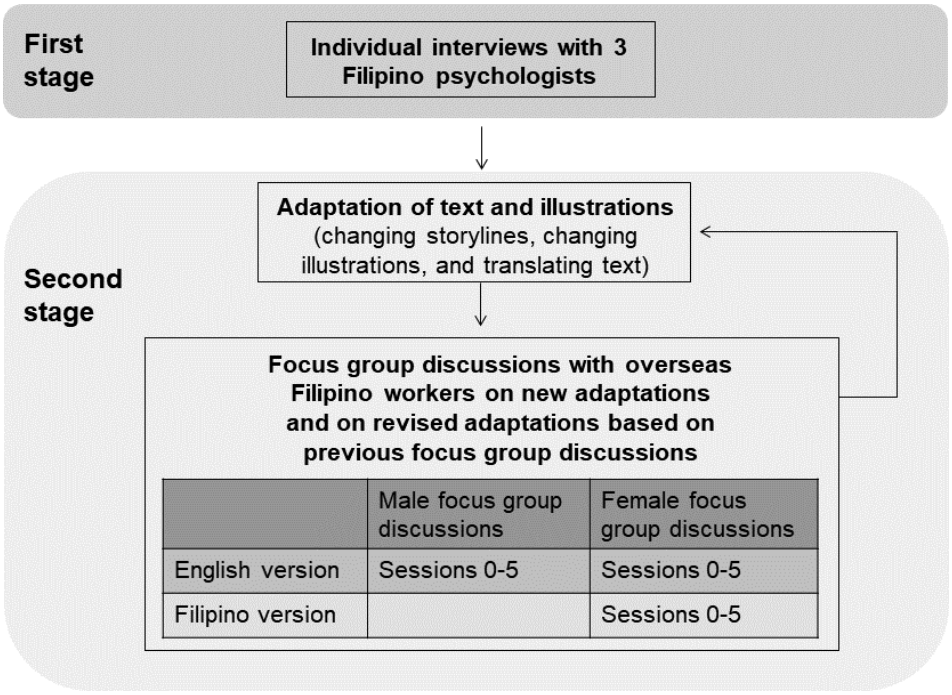
The intervention material was a generic version of the Step-by-Step program. The program starts with registration and introduction (session 0), followed by sessions 1 to 5. Each session is meant to be completed on the Web by the user once per week, with each session lasting between 30 and 40 min.

In advance of the interviews with expert Filipino psychologists, we provided a summary of the program's content, the complete intervention content, and examples of possible illustrations with instructions to review all materials before the interview. For the FGDs with OFWs, we made Microsoft PowerPoint presentations that showed the entire initial adapted texts and illustrations (after Filipino psychologist interviews). Each slide consisted of about 3 to 5 sentences, most with simple illustrations.

We started only with the intervention text for sessions 0 to 2, as the illustrations were not yet ready. Eventually, we showed both texts and illustrations to the participants side by side for the remaining 3 sessions.

We also utilized interview and FGD guides. The interview guide for the psychologist interviews consisted of questions about their opinions on whether or not the Step-by-Step program can address OFWs' mental health needs, the type of OFWs that the program will be most or least suitable for (ie, hotel staff and domestic workers), appropriateness of the content of the program, considerations we had to make with regard to Filipino culture and OFW culture, and challenges they foresaw in using the program. We added questions on which specific groups we needed to consider for content tailoring (eg, younger or older OFWs), suggestions on the characters in the story, and opinions with regard to the characteristics of the eHelpers. For the FGDs with OFWs, we started cognitive interviews (a technique whereby participants think aloud [28]) with a broad question on what participants thought about each of the PowerPoint slides. We then probed, using open-ended questions, if the content is relevant or relatable, understandable, or acceptable and the ways by which we can improve the text or illustrations. We also asked if the text and illustrations on each of the slides match, and if not, how we can change the text or illustrations to ensure they correspond with each other. When asking these questions, we told participants to think about all OFWs globally (eg, Would all or most OFWs understand this text?) and not just themselves or just OFWs in Macao to increase generalizability to OFWs across ages, marital statuses, occupations, and countries where they are employed.

Figure 1. Flow of the adaptation process.



Procedure

FGDs were conducted in English to adapt an English-language version and in Filipino to adapt a Filipino-language version. We matched the sex of the facilitator with the sex of the participants (ie,

male facilitator during male FGDs).

We first gave participants consent forms to read and sign, and then, we introduced the interview or group discussion and the Step-by-Step program. We then proceeded with the interviews or FGDs. The first FGDs concerned developing the illustrations of the main characters. After this, once illustrations had been developed, further groups were conducted based on the remainder of the stories and activities. The entire adaptation process was thoroughly documented. We used note-taking, wherein we wrote participants' feedback for each slide. We also used audio recording to review the sessions if any of our notes were unclear. After an interview or FGD, we (MRG and BJH) discussed what transpired and reviewed our notes. We decided on pertinent changes that needed to be made on each slide. Throughout the process, we used the approach of Manson [16] and van Ommeren et al [17] in that we focused on adaptations that would better ensure relevance, acceptability, and comprehensibility to as many OFWs as possible, while retaining completeness of the Step-by-Step program. When participants' opinions differed in terms of whether to make changes or not (ie, a sentence was understandable to some participants but others suggested to simplify or provide more explanation), we decided to make adaptations to ensure the content was appropriate to the broadest possible audience, and these modifications were then brought back to the community for any further comment and approval. When there were varied suggestions on how to adapt text and illustrations (ie, different suggestions on what words to use or how to change illustrations), we chose what the majority preferred and what was applicable to most OFWs (ie, applicable to the majority of male and female OFWs, young and old).

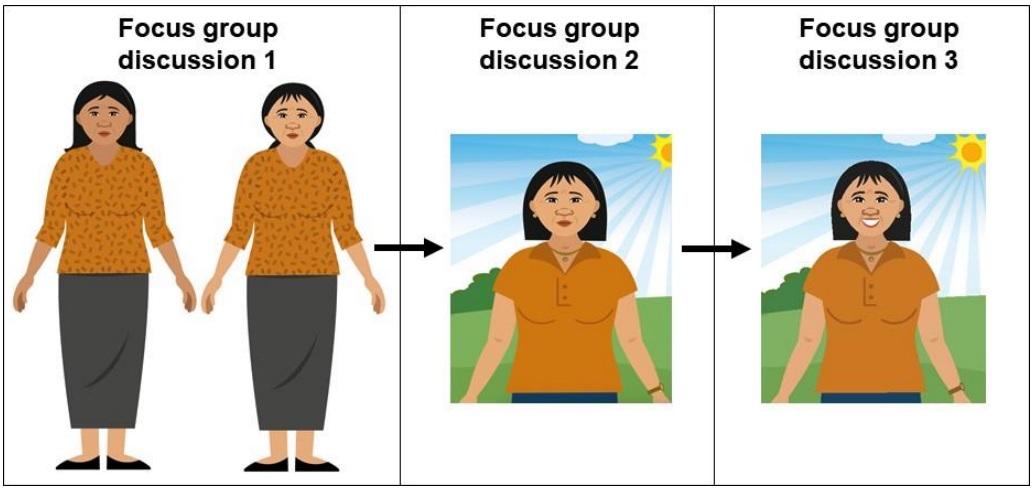
All changes in text and illustrations were documented using standard forms developed by the World Health Organization. We deemed making changes based on our notes sufficient because participant feedback on the slides was simple and straightforward (ie, participants mentioned which sentences were confusing, and they shared which part of the illustrations did not match the text), and participants provided us with concrete suggestions on what changes to make (ie, they suggested words to use and what to add or omit in the illustrations). Furthermore, each slide contained relatively short text and simple illustrations to begin with. The questions we asked them were also direct (ie, Can most OFWs understand the text? How might we improve the text to make it more understandable? Can you relate to the character? How might we make the character more relatable?).

Suggested changes to the illustrations were sent to a professional illustrator. He was the same illustrator who made the illustrations for the original Step-by-Step program and was familiar with the program and cultural adaptation process. Using the original illustrations as the starting point, we gave instructions on what changes to make (ie, character's facial expression should be happier or omit certain hand gestures) and at times accompanied instructions with sample photos taken from the internet to guide the development of new illustrations.

Changes in illustrations and in stories were then shown to participants during subsequent FGDs. We reminded participants of their comments on the past illustrations and text and showed them the revisions made. We asked for their feedback on the changes and then their approval (ie, Is this what you meant? Anything else that is unrelatable, unacceptable, or hard to understand?). If the changes were still unsatisfactory, we asked for more input from them, made necessary revisions, and then showed them the newly revised slides in the next FGD. For example, it took 3 FGDs to finalize the appearance and get participants' approval for one of the characters (refer to Figure 2).

After we conducted all the FGDs on the English and female versions and after revising the texts, we sent the texts to a professional translator. The translator was a Filipino fluent in both Filipino and English, with a BA in *Malikhaing Pagsulat* or Filipino creative writing. We gave her a background of the adaptation process and informed her of the desired tone of the story and personality of the characters as per the interview and focus group feedback. We then edited the translated text to capture the OFW experiences better (ie, words they often used in FGDs to describe their experiences). The edited translations were then shown to female FGD participants during subsequent cognitive interviewing. Their comments and suggestions to simplify the texts, especially words that were too difficult to understand or lines that were too long, were then used to make additional translation edits. We then showed the revised slides during the next FGD for feedback and approval

Figure 2. Character adaptations. In focus group discussion (FGD) 1, two sample illustrations of the main character were presented to participants for feedback with regard to appearance. Participants gave vivid descriptions on how they wanted her to look (ie, short hair with bangs, with jewelry, etc) In FGD 2, revised illustration based on FGD 1 feedback was shown to participants who gave partial approval. They liked how the character looked but not her personality. Participants suggested making her appear warm and happy. In FGD 3, revised illustration based on FGD 2 feedback was shown to participants, who then gave full approval.



Reflexivity and Procedures for Verification

This study was conducted by a research group that aimed to improve the health of migrants globally and within the Macao SAR. As such, the implementing researchers (MRG and BJH) were familiar with the OFW context, through prior knowledge and interactions with the study population, and worked with organizations providing support to this community (eg, Philippine Government, churches, and NGOs) for years, including those based in the Macao SAR. MRG is a native Filipino who speaks the Filipino language fluently and has a similar cultural background as the participants. During data collection, MRG was an OFW herself but was only involved in the project as an investigator but not a participant. BJH is from the United States of America and emigrated to China over 5 years ago. However, neither researcher is employed in the same sector as the participants. We also had higher educational attainment, occupational prestige, and socioeconomic status. Although we are migrants ourselves and have a rich understanding of the OFW context, our experiences are different from the

participants' and other typical OFWs. With this acknowledgment, we attended to our own beliefs by assuring participants their feedback on the materials were crucial in improving the program and that they were the experts when it came to OFW experiences. We also probed participants' answers to get more information and asked them to confirm our understanding of their input. Furthermore, we presented to them the interim changes we made on the stories and illustrations for validation. They verified many of the changes, but at times, they provided clarifications and more details for additional changes. We also presented the findings to a group of stakeholders, which included Philippines Government staff (Consul General, Labor Attaché), NGO workers, a Macao government official, Macao mental health professionals, and Filipino priests and nuns, for their feedback. They did not suggest changes in the adapted program and instead raised concerns regarding logistics and eHelpers.

Results

Acceptability

On the basis of key informant interview data and FGD data, there were 3 main issues with regard to the acceptability of the generic version of Step-by-Step. This includes stigma regarding mental health problems and mental health help-seeking in the Philippines. On the basis of interview data with experts, the use of a doctor pathologises the users' experiences and connotes there is something wrong with them. This would then serve as a barrier for the OFW population to use the program. This opinion is also backed by previous research [29]. Another issue was, from the participants' viewpoint, that some of the original content was politically charged or socially unacceptable to all OFWs. For example, the initial illustrations included hand gestures that reminded participants of political parties.

The text also mentioned drug use as a negative coping strategy, but participants shared that this was reminiscent of the popular but polarizing drug war campaign of the current administration in the Philippines. Another example was illustrations that depicted the characters doing household chores, which leaned too much toward domestic work. Although many OFWs are skilled workers, there are many professionals such as nurses, managers, and teachers as well, which makes doing household chores unsuitable for all OFWs. Other instances were coping strategies originally depicted as negative but are normative or even positive coping strategies in the OFW context. For example, an illustration and text were about a character staying in bed all day, but participants shared that for OFWs in physically demanding jobs, this is a good strategy to recover from stress at work. Another was *drinking alcohol* because it is culturally normative for Filipinos to drink, especially when they are with their friends. Finally, some male participants mentioned that some text and illustrations looked too feminine (ie, crying in bed). Due to strong traditional gender roles, it was important for them to maintain a masculine stance or at least not exude femininity, including emotional weakness.

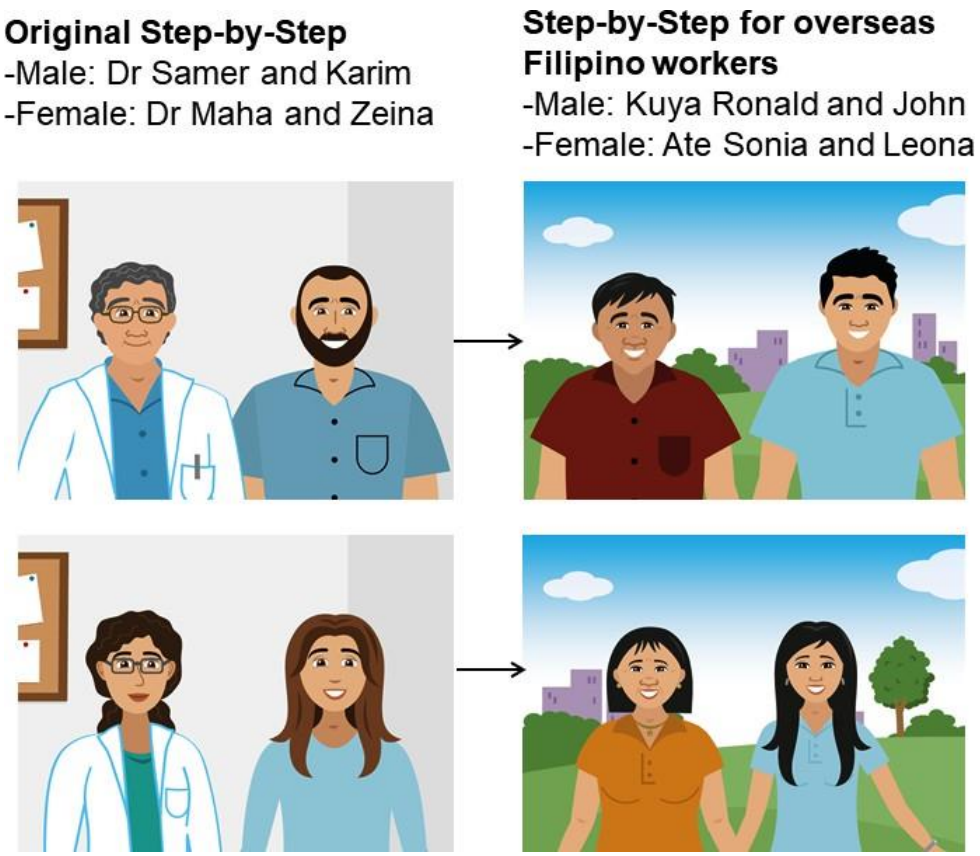
To address these issues raised by participants, adaptations were then made to make Step-by-Step acceptable. These include reducing content that may increase the stigma associated with mental health and help-seeking, changing content that appeared political or potentially unacceptable to an OFW subgroup and depicted as negative when it is socially acceptable in the OFW's context, and making considerations for the male version. These are explained below.

To address the issue of stigma, we made 3 modifications. First, instead of stating the original program goal of "helping the user cope with difficult emotions and problems" explicitly, we changed it to "helping the user become a successful OFW, for their families' sake." The latter deemphasizes the focus on mental health and increases emphasis on positive goals and outcomes. The latter also still addresses the original goal but focuses on a common and integral OFW experience and value of working abroad to contribute to family's expenses, at times as the family's sole provider. Second, we developed the character that explains Step-by-Step concepts to the user (ie, stress and sadness) into an older OFW who has been successful in his or her work rather than a medical or mental health professional (refer to Figure 3). Changing the character to a fellow OFW normalizes the experience of problems and removes the stigma. Furthermore, interview and FGD data showed that making the character successful incorporates the aspirations of the target group. Third, we changed text such as "suffering at the moment" to "stressed at the moment" to make them sound less grave and more normative, as advised by FGD participants.

Some of the content was removed from Step-by-Step or changed. We removed certain hand gestures and drug use as a negative coping strategy to make the program apolitical. We removed the illustration and text about a character staying in bed all day as a negative coping strategy because this is an acceptable, even helpful, coping strategy for OFWs. We changed the illustration on characters doing household chores to sending remittances in a bank and filling up a package or what Filipinos call *balikbayan box* (literal translation: back to country) to the Philippines and preparing to go to work (refer to Figure 4) to be more neutral and suitable across occupations. These are ubiquitous OFW experiences, regardless of job or socioeconomic status. Another is "drinking alcohol," which we changed to "drinking too much alcohol." Participants recommended adding the term "too much" to make it a negative coping strategy.

We also made considerations for the male version. As much as possible, we ensured that female and male versions had similar storylines, activities, and illustrations so as to limit gender stereotyping as much as possible. However, for some illustrations, we made them slightly different to appeal to male OFWs by avoiding what male FGD participants believed to look too feminine. For example, in a scene that shows the character is isolated from others, the male character is in his bedroom looking lonely, with legs in v-position, elbows resting on his thighs, and hands clasped together. In the female version, the character is still alone in her bedroom but is in fetal position and hands covering her face (refer to Figure 5).

Figure 3. Illustration of characters in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.

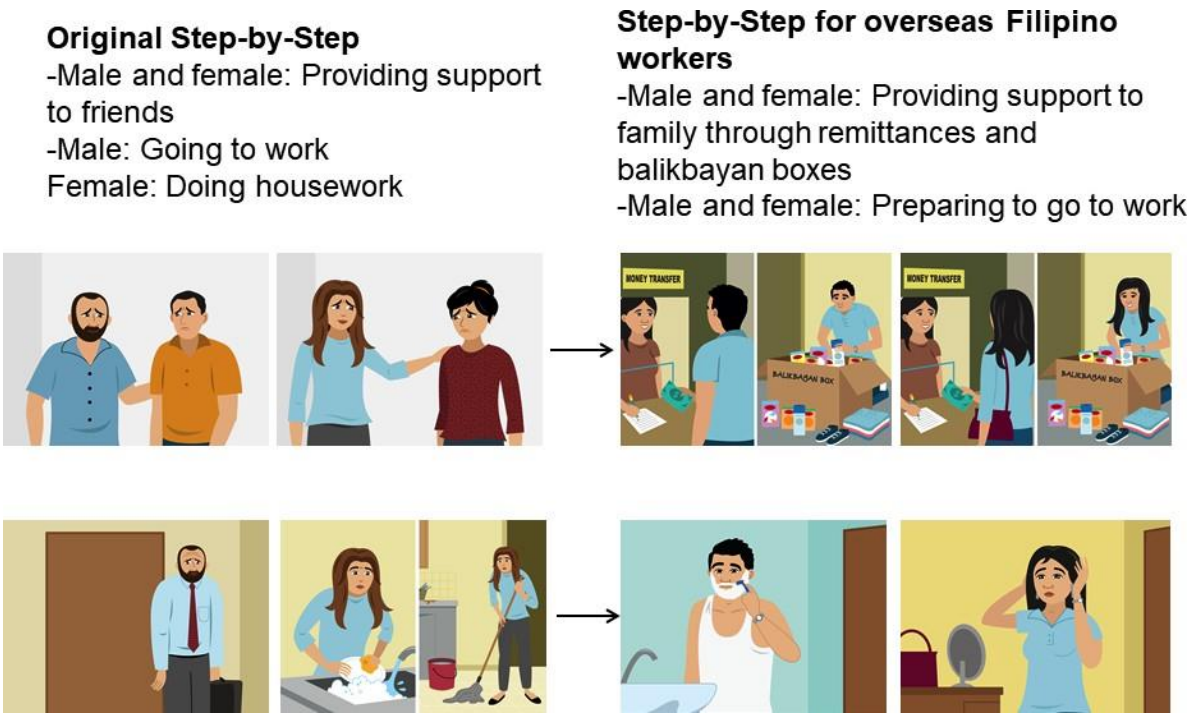


Relevance

There were 4 issues with regard to the relevance of the original text and illustrations of Step-by-Step. The first issue was in terms of the characters. The generic version used Lebanese and Muslim characters (ie, characters have names like Zeina and Karim, females wore hijab, and males had thick beards; refer to Figure 3), which were different from typical Filipino names and appearance.

The second issue was in terms of the lack of relatable values in the stories. For example, participants found the tone of the stories and personality of the characters to be too serious and robotic, which they felt were not attuned to the Filipino value of showing warmth and hospitality. The third and fourth issues were in terms of the lack of relatable problems and activities. Some of the problems in the generic version included destruction of one's home and community. Although these happen to some OFWs, participants felt these were not the most pertinent problems in their community. Moreover, participants deemed some of the activities in the generic version atypical or unfeasible, such as planting herbs and spending time with family. These were irrelevant to OFWs because while abroad, there is no ample space to plant herbs, and OFWs cannot be physically together with their families. Participants added that planting herbs would not come across as a fun activity for many OFWs. To increase relevance, we made the following adaptations: (1) choosing appropriate names and appearance of main characters, (2) highlighting Filipino values, (3) using relatable problems, and (4) using relatable activities.

Figure 4. Illustration of providing support to others in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.



We first developed the characters' names and appearances to make them sound and look Filipino. The older characters had Spanish-sounding names (Kuya Ronald and Ate Sonia), whereas the younger characters had more modern and American-sounding names (John and Leona), both of which are common naming practices that are related to the colonial and changing cultural context of the Philippines. We also ensured that the names had positive meanings (ie, a wise person and a fighter) and were approved or chosen by the participants. For the older characters, we added the terms *Ate* or *Kuya* before their names, which mean respected older sister or older brother in Filipino, often associated with being sensible and experienced. For the characters' appearances (refer to Figure 3), participants wanted their hair straight and black and their skin colour warm or olive in tone. The participants also wanted the characters to look successful as they link being a migrant for years to having saved money and made investments but added that they needed to dress comfortably as they are busy at work. They proposed making their clothing simple, comfortable but modern, and adorned with jewellery such as watches for the male characters and earrings, necklaces, and watches for the female characters.

We highlighted Filipino values in 3 ways. First, experts and participants advised adapting the personality of the program and characters to exude desirable Filipino values of family orientation, showing warmth and care for others, sociability, and positive thinking. Participants added changing the tone of the text to become more conversational and story-like to sound more engaging and realistic such that the characters seem to be talking to the users. Participants also recommended that the characters addressed the user as *kabayan* or countryman, a common term used among OFWs, which denotes similarity and familiarity with fellow Filipino migrants. The older characters also acted as mentors or coaches to the younger characters and user. The younger characters called the user *sis*

or *bro* to denote kinship. They showed eagerness to share their stories and emotions with the users and to learn and become better. Participants advised for all characters to offer encouragement or reassurance to the user, with lines such as "Keep up the good work!" and "You can do it!" They recommended matching these with illustrations where the characters gave warm smiles to welcome and bid the users goodbye and thumbs-up sign to show approval.

Figure 5. Illustration of isolating oneself from others in the original Step-by-Step version and in Step-by-Step for overseas Filipino workers.

Second, the texts were changed to highlight that OFWs consider their family as motivation for going abroad and working hard, even making sacrifices for them. Participants suggested matching the illustrations by showing OFWs thinking of their families often and missing them. Furthermore, participants wanted to emphasize being with friends and family as crucial to one's mental health and as culturally appropriate and expected. Participants proposed matching the text with illustrations of characters spending time and having fun with friends who were also OFWs and with family through Web-based communication.

Third and last, as suggested by all 3 experts during individual interviews, we mentioned additional Filipino values such as bayanihan and utang-na-loob in the stories. Bayanihan means working together to help someone, which we added in an activity where an OFW helped a main character in a task. Utang-na-loob means debt of gratitude, which we mentioned as a motivator for a main character to reach out to a friend who helped them in the past.

We adapted the content in terms of the problems the characters experienced to make them more

typical, based on interview and FGD data. Examples of problems included leaving their family behind, having personal conflicts, and having too much work or having no break or day off.

We likewise adapted the content in terms of the activities the characters engaged in to make them enjoyable and doable to as many OFWs as possible. On the basis of FGD data, examples include eating *merienda* or afternoon snacks with friends, visiting nearby historic sites, celebrating events with family using Web-based communication, and singing videoke (video karaoke) with friends (refer to Figure 6). These are typical fun activities that Filipinos engage in. Filipinos are fond of eating meals together, exploring new sites when abroad, connecting with families back home, and listening to music and singing. These activities are also relatively inexpensive and not that time-consuming, which make them feasible to do during days off and even with limited finances.

Comprehensibility

The generic version of Step-by-Step had elements that were incomprehensible, unclear, or too complex. In the text, there were sentences that participants deemed too long or repetitive and, therefore, difficult to understand. Some participants expressed finding some terms (ie, *peers*, *pace*, and *social support*) complicated. Finally, participants found that some texts and illustrations were not clearly linked. For example, one passage in the text was about isolating oneself from other people when one feels sad. Although participants understood the text, they mistook the illustration where the character is facing away from 2 other characters as friends gossiping about the character (refer to Figure 5).

To make the adaptation comprehensible, we used Filipino and English languages. Filipino is the national language in the Philippines. Both Filipino and English are official languages and are widely spoken by OFWs as primary mediums of communication, that is, Filipino with fellow OFWs who come from different regions in the Philippines and English with their employers. Filipino is derived from Tagalog, the main language of 35.1% of households in the Philippines [30].

On the basis of FGD data, we also simplified the text in 3 ways to boost comprehension: shortening long sentences by removing words, dividing long sentences into 2 sentences, and using simplest words and phrases (i.e., changed the word peers to friends and pace to speed). When a term or an idea was too abstract, we changed the words or added extra words or lines to clarify what they meant. For example, instead of the abstract concept of social support, we used helping hands as suggested during an FGD because although participants understood what social support meant, they could not verbalize their understanding of the term.

For the Filipino version, participants suggested simplifying text by removing sentences when paragraphs sounded repetitive and confusing. We retained those lines in the English version as they did not sound repetitive in English. Moreover, some English words or phrases when translated to Filipino sounded awkward; hence, we retained the original words in English. For example, we retained the word congratulations because its Filipino translation of binabati kita or “I compliment you” sounded odd to participants. We removed English words or phrases that did not translate well into Filipino, as suggested by participants. We adapted texts and illustrations that were not clearly linked, following participants’ recommendations. For example, for the illustration about isolating oneself, we had the illustration changed so that the character is in bed alone (refer to Figure 5).

Figure 6. Illustration of enjoyable activities in Step-by-Step for overseas Filipino workers.

Completeness

All key concepts in the original version are intact in the adapted Step-by-Step for OFW. We also made sure that the English and Filipino versions were as similar as possible, so that if an OFW chooses to use the English version, they would have an equivalent program to the Filipino version and vice versa. For the Filipino version, instead of translating all English words to Filipino, we retained some English words because OFWs use these words to describe their experiences. The combination of Filipino and English (ie, Taglish) is an unofficial language [30] that is normative and accepted among Filipinos. An example is being *homesick* as they are away from their family. Participants recommended retaining the English word *homesick* instead of using the Filipino translation of *hinahanap-hanap ang pamilya* (yearning for family) because the word homesick is a common OFW term and is deeply tied to working abroad far from one's family.

Discussion

Principal Findings

To our knowledge, this is the first study that culturally adapted an e-mental health intervention for the OFW population and Filipinos generally. We illustrated how the 4-point framework to improve acceptance, relevance, comprehensibility, and completeness is useful in navigating the process of culturally adapting the Step-by-Step program. It was a practical guide to both us, the researchers, and the participants as it enabled us to capture and flesh out crucial elements to make the finished product attuned and sensitive to the context and experiences of OFWs. In turn, we were able to make the program culturally specific for this group, which is essential among the 4 features of effective e-mental health interventions [15].

Lessons Learned

For future cultural adaptations, we recommend that all illustrations and content be adapted at the same time. In our experience, participants were more engaged in the presence of visual stimuli (recall that we were not able to present illustrations for sessions 0-2). Furthermore, it was easier for them to understand the texts and key concepts while being able to see the illustrations.

We recommend that the same set of participants be part of the FGDs from start to finish to avoid spending time explaining the program, the mechanics of the cognitive interviews and discussion, and details from previous sessions. We were able to do this with the majority of our FGDs, but scheduling limitations hindered participants from attending all sessions. Therefore, to accommodate the realities of the population, we allowed the FGDs to be open to newcomers. Some participants were more able to provide input than others. As in any FGD, it is important to select participants who are more open, less shy, and comfortable to freely share their thoughts. In the context of this adaptation study, norms of social hierarchy and harmony within the cultural group may have influenced how much people shared within the groups.

Another limitation is the lack of standard and systematic evaluation on whether the inputs from members of the FGD represent the entire community. Further investigation is also recommended to determine which elements were most salient to the participants to more clearly know when adaptations are good enough for the cultural group.

Relevance of the Research

The methods and detailed results of formative adaptation work as described in this study are often not shared by researchers or program implementers in mainstream literature [9,11]. As it is such a crucial step in planning and care provision, we hope that this study will not only highlight the importance of cultural adaptation but also provide the audience a replicable account of how to conduct such formative research.

Following the Medical Research Council Guidelines for Complex Interventions and the WHO scalable psychological interventions program [31,32], this adapted program will be rigorously evaluated. The initial feasibility trial and subsequent full-scale randomized controlled trial both include process evaluation components. Subsequent changes to the illustrations, content, and program story will be made, if needed.

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Conflicts of Interest

None declared.

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Abbreviations

EBT: evidence-based treatment
e-mental: electronic mental
FGD: focus group discussion
NGO: nongovernmental organization
OFW: overseas Filipino worker
SAR: Special Administrative Region

Chapter 7: Step-by-Step feasibility testing in Lebanon

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Step-by-Step, an e-mental health intervention for depression: a mixed methods pilot study from Lebanon

Abstract

Background: E-mental health is an established mode of delivering treatment for common mental disorders in many high income countries. However, evidence of its effectiveness in lower income countries is lacking. This mixed methods study presents preliminary data on the feasibility of a minimally guided e-mental health intervention in Lebanon. The aim was to pilot test Step-by-Step, a WHO guided e-mental health intervention prior to future, controlled testing.

Methods: Participants were recruited using social media and advertisements in primary care clinics. Participants completed baseline and post-intervention questionnaires on depression symptoms (primary outcome, PHQ-8), anxiety symptoms, wellbeing, disability and self-perceived problem severity and a client satisfaction questionnaire. In addition, seven completers, four drop-outs, eleven study staff and four clinic managers were interviewed with responses thematically analyzed. Website analytics were used to understand participant behavior when using the website.

Results: A total of 129 participants signed up via the Step-by-Step website. 74 participants started session 1 after completing pre-test questionnaires and 26 completed both baseline and post intervention data. Among those who completed post-assessments, depression symptoms improved (PHQ-8 scores ($t=5.62$, $p<0.001$ 2 tailed, $df=25$). Wilcoxon signed ranks tests showed a significant difference between baseline and post-Step-by-Step scores on all secondary outcome measures. Client satisfaction data was positive. Interview responses suggested that the intervention could be made more appropriate for younger, single people, more motivating and easier to use. Those who utilised the support element of the intervention were happy with their relationship with the non-specialist support person (e-helper), though some participants would have preferred specialist support. E-helpers would have liked more training on complex cases. Website analytics showed that many users dropped out before intervention start, and that some re-entered screening data having been excluded from the study.

Conclusion: Step-by-Step skills and techniques, model of service integration and non-specialist support element are acceptable. Though the sample was small and non-controlled and drop-out was high, results suggest that it may be effective in reducing depression and anxiety symptoms and increasing wellbeing. Lessons learned will inform content revision, the development of an app version of Step-by-Step and the research methodology of upcoming effectiveness studies.

Introduction

The evidence for the efficacy of e-mental health is so compelling that e-mental health programs have been included in a number of countries' national mental health strategies and treatment guidelines, including the Netherlands, the United Kingdom, Australia, New Zealand, Sweden (75) and since 2015,

Lebanon (56). However, very little of the evidence supporting e-mental health comes from low- and middle-income countries (76,77) or conflict or post-conflict settings.

E-mental health programs can be unguided and fully automated, or can be guided, whereby the user receives written, telephone or face-to-face support from a health worker or trained layperson. Systematic reviews of the comparative effectiveness of guided versus unguided e-mental health interventions show that effects are higher when an intervention is guided, for example d=0.78 guided versus d=0.36 unguided (78) and that the support can be beneficial regardless of the qualifications of the supporter or the type of support offered ((44,78). WHO treatment guidelines for depression recognize the potential of guided and unguided self-help to vastly improve treatment coverage at a public health level (79).

Lebanon is a middle-income country in the Middle East with a long history of complex political turmoil and conflict. Civil war, border tensions, war with neighbouring countries and the conflict in Syria have all deeply impacted Lebanon and its health system. The United Nations High Commissioner for Refugees (80) reports more than 1.5 million registered Syrian refugees and many more undocumented persons of concern residing in Lebanon, further stretching Lebanon's already limited resources.

A national representative survey (n=2857) conducted in Lebanon before the Syrian conflict showed that one in six people met criteria for at least one mental disorder, with 27.0% of these classified as "serious" and of those with a mental disorder, just one in nine (11%) had ever obtained any treatment (81). It is to be expected that this situation has worsened since the survey was conducted, especially considering the more recent influx of displaced persons affected by the conflict in Syria.

Ministry of Public Health (MoPH) data from 2015 highlighted that the main problems in accessibility to mental health services are physical and financial, with mental health services being centered in urban areas and mostly in the private sector at an elevated out-of-pocket cost. The MoPH has worked extensively with the support of WHO on reforming this sector by integrating mental health care into its network of public Primary Health Care Centers (PHCC). Nevertheless, the lack of stable financing, the lack of services in rural areas and the prevalent stigma against mental health remain the major barriers to accessing care. This all contributes to the MoPH-estimated mental health treatment gap of 90% in Lebanon and highlights the importance of a mental health intervention that can be delivered widely despite the limited human resources, limited funding and stigmatizing beliefs that currently reduce access to care.

A substantial proportion of the population in Lebanon has regular access to mobile phones (81%) and the internet (76%) (82). With regard to Syrian refugees in Lebanon, 100% have 3G coverage (80). These data, coupled with high literacy rates and high need mean that e-mental health could represent an important opportunity to overcome cost, stigma and other access issues in mental health care provision to increase access to evidence based interventions. Investigating e-mental health as a service delivery strategy has been included in the MoPH Mental Health Strategy for Lebanon 2015-2020, currently under implementation by the National Mental Health Programme at MOPH.

The MoPH in Lebanon has partnered with the World Health Organization (WHO) to test a WHO digital intervention called "Step-by-Step" (83). Step-by-Step (SbS) is a brief, minimally guided self-help program for people with depression (see description below). The aim of this paper is to present the results of a preliminary, uncontrolled pilot study on a website version of SbS, including information on other elements of the process such as web analytics data from the website.

Methods

Pilot study

We assessed SbS in a small uncontrolled pilot study with the aim of informing further development of the intervention and to inform the design of randomized controlled trials. In addition to collecting pre- and post-measures, we also conducted a qualitative process evaluation.

Intervention

SbS (Khoutweh-Khoutweh in Arabic) is a five session online intervention using behavioral activation and stress management techniques designed to ameliorate symptoms of depression (83). It has been designed as a scalable self-help intervention, which may or may not be coupled with guidance from a health worker or other helper. SbS can be accessed through a website using a smartphone, tablet or computer. It is presented using a narrated story with interactive exercises to apply the techniques learned through the story to the users' own life. SbS was systematically translated and adapted to the Lebanese context, the details of which can be found in a separate paper (84). More detailed information about the intervention can be found in Carswell et al 2018 (83).

Potential participants (see below) visited the website (either in English or in Arabic), where a short recruitment video and a how-to sign-up video could be found. Users would find out if SbS could be suitable for them by completing the PHQ-9 screening questionnaire. Upon completing screening and meeting inclusion criteria, participants could set-up an account, view all study information and complete the informed consent procedure, with the possibility to contact study staff with questions or problems signing up. After consenting, they were taken to a brief introduction session where a story character presented each baseline measure for the participant to fill in. Baseline assessment was followed by a brief exercise to identify personal strengths and a relaxation exercise, in case participants felt anxious about their symptoms due to completing the pre-assessment questionnaires. They were then able to start the intervention three days later, with sessions being released every four days. Participants had eight weeks to complete the subsequent five sessions of Step-by-Step before being prompted to fill in post-assessments. Tablets were placed in private rooms in five of the participating PHCCs in order to provide access to those who may not own a smartphone or have access to the internet.

Throughout the intervention, trained psychology and public health graduates (referred to as "e-helpers") could offer minimal assistance to Step-by-Step users (if desired by the user) through 15-20 minutes of weekly phone calls or email messaging. This assistance included technical website support, motivational support and clinical support such as simple problem solving and troubleshooting SbS exercises. E-helpers were non-specialists trained over six days by study staff on

the intervention as well as on mental health conditions, communication skills and working with distressed people. They received group clinical and management supervision every two weeks, as well as on-demand telephone clinical supervision with a clinical psychologist. Users did not have to accept e-helper support in order to use Step-by-Step, but they were encouraged to do so.

Study population and recruitment

The target population included male and female Lebanese, Palestinian and Syrian participants who self-reported as over the age of 18, were resident in Lebanon, scored above a locally established cut off of 10 or above on the PHQ-9 ((85) and were not at risk of suicide (according to item nine on the PHQ-9 screening questionnaire and two follow-up questions). Participants provided informed consent as part of the sign-up procedure.

Recruitment began in October 2017 through seven government-supported PHCC across the country and two Beirut private family health clinics. Posters and leaflets were placed in waiting rooms with a short video where screens were available and a trained focal point at each center provided information about the study. We also conducted two social media advertisement campaigns through the MoPH Facebook network and posted advertisements and recruitment links on two Beirut University Facebook and WhatsApp groups. Recruitment took place over six months using non-stigmatizing language in any recruitment materials with images showing people from ambiguous socio-economic status (SES) and religious backgrounds.

Outcome measures

The primary outcome of the pilot study was depression symptoms measured using the PHQ-8 (85,86), which was also repeated at the beginning of each Step-by-Step session. The PHQ-8 contains the same items as the study's screener, the PHQ-9, minus the item on suicide ideation. Secondary outcome measures were the WHO Disability Assessment Scale (WHODAS) 2.0 (87), General Anxiety Disorder seven (GAD-7) (85,88), WHO-five wellbeing index (WHO5, (89) and the Psychological Outcomes Profile questionnaire (PSYCHLOPS) (90), a self-report problem rating scale. We also provided a satisfaction questionnaire at post-assessment which was adapted from the Client Satisfaction Questionnaire (91).

For ethical reasons, participants could skip a question if they did not want to answer it. This led to some missing values, which were imputed by taking the mean of the other item responses of the measure and rounding this down or up to the nearest integer.

Analysis

Data was collected by the web program and downloaded into Stata version 14 and into Comprehensive Meta-Analysis version 3.3.070. Descriptive statistics and simple tests of statistical differences were run. Despite the study not being powered to detect effect sizes, as an effect size calculation for completers gave a crude idea of the magnitude of the effects of completing Step-by-Step. Effect size was measured as the difference between the means divided by the pooled standard deviation and adjusted for the correlation between pre- and post-intervention total PHQ-8 score.

When checking for skewness and kurtosis of the small data set of completers only, data was found to be right-skewed for all measures apart from the PHQ-8 either at pre- and/or post-assessment. We

therefore carried out a t-test and effect size calculation on PHQ-8 data and Wilcoxon matched pairs signed ranks tests on the other outcome measures.

Process evaluation and web analytics analysis

The process evaluation comprised one-hour long interviews with 11 participants in the study (seven of these had completed the intervention and four had dropped out, i.e. completed less than four sessions). Study participants were asked during their support sessions or in the PHCC if they wanted to participate in a telephone or face-to-face interview after the study (face-to-face interviewees were offered 10USD to cover travel expenses). Of those who had accepted, 11 were selected at random towards the end of the study period. All participants provided verbal informed consent on the phone prior to the interviews. Participants were diverse with regards to nationality, gender, marital status and area of residence. Interviews were conducted by phone or face-to-face, depending on the preference of the participants. Those who attended the face to face interviews were remunerated 10$ for transportation. In addition to interviews with participants, interviews were conducted face-to-face with the four e-helpers, the clinical supervisor, six front line workers from several PHCCs and four directors of PHCCs.

A semi-structured interview schedule was used to guide the discussion with participants. This schedule included questions on five main themes: overall experience, intervention content, rapport with e-helpers, intervention adherence and burden of assessments (see appendix 1 for an example interview schedule with completers). Interviews were recorded and transcribed. Interviews were carried out and analyzed by the local project coordinator (JAR) and a consultant research assistant (recruited to carry out some of the interviews with project staff in order to minimize bias in responses).

Interview data (in the form of notes) was recorded, transcribed, translated into English and thematically analyzed. Responses were categorized into themes by one of the two data collectors (JAR) and a third team member checked the thematic coding against the original recordings or notes of the interviews (EH). Discrepancies in thematic coding of information were discussed between data collector and the data checker.

Available website analytics were compiled using the Matomo (Piwik) web analytics application V3.3.0, including information about the number of visits to the site, descriptive data on the number of sessions completed by participants, weekly depression scores and number of participants who dropped-out.

Results

Demographic and usage data

Out of 149 applicants, 129 completed the baseline assessment and met inclusion criteria (of which 100 were female). Their mean age was 27.7 years old (range 18-70). Demographic characteristics are displayed in Table 1.

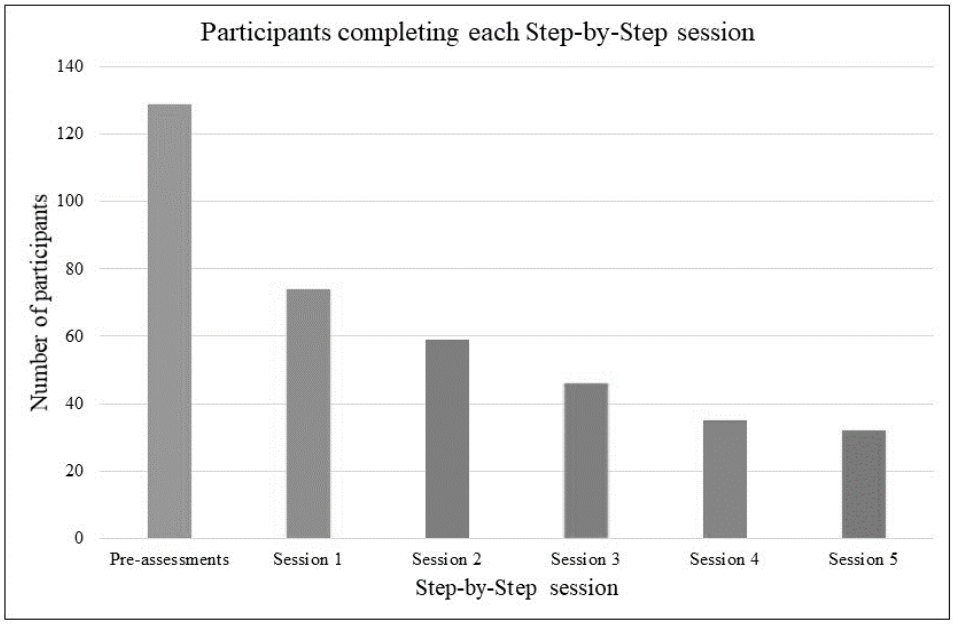
Table 1. Characteristics of study participants who chose to provide demographic information.

Demographic characteristic	**Frequency**
Nationality (n=126)	
Lebanese	111 (88%)
Palestinian	8 (6%)
Syrian	5 (4%)
Other	2 (2%)
Gender (n=129)	
Female	100 (78%)
Male	29 (22%)
Highest level of education (n=124)	
Primary school (3-6y)	1 (1%)
Elementary (6-14y)	3 (2%)
Secondary school (15-17y)	14 (11%)
University (18+y)	97 (78%)
Technical school (18+y)	9 (7%)
Occupation (n=128)	
Employed paid	44 (34%)
Non-paid work	2 (2%)
Student	41 (32%)
Homemaker	12 (9%)
Unemployed	23 (18%)
Other	6 (5%)
Location (n=127)	
Beirut	54 (43%)
Outside Beirut	65 (51%)
Outside Lebanon	8 (6%)
Marital status (n=123)	
Never married	75 (61%)
Currently married	35 (28%)
Separated	6 (5%)
Divorced	6 (5%)
Widowed	1 (1%)

We had envisaged to recruit 200 people in six months, but we struggled to recruit this number of participants, with particularly low numbers of non-Lebanese nationals (5/126 Syrians and 8/126 Palestinians). Of the 126 people who responded when asked "how did you find out about Step-by-Step", 81 stated they heard about SbS via the web (Facebook being the only website we recruited through) and 20/126 had heard about it through a friend. 20 people selected via a health centre (either from a health worker or by the flyers and posters placed in health centers). Of the Palestinians who did sign up, all eight were recruited in the health center of a refugee camp.

Figure 1 shows the number of participants that completed each session of the intervention. 55 (43%) of the 129 participants did not start session one after they had signed up and completed baseline assessments. 26 of those 74 (35%) participants who started SbS completed post-treatment questionnaires. 32 of 74 participants (43%) who started completed all five sessions and 35 (47%) completed between one and four sessions. All but three people who reached session four went on to complete the intervention. For the purposes of this study, we considered a completer to be anyone who started session 1 and completed at least four of the six sessions (n=35), meaning that Step-by-Step had a drop-out rate of approximately 50%.

Figure 1. Number of participants that completed each Step-by-Step session



Characteristics of those participants who signed up but never returned to the Step-by Step website site were broadly similar to those who reached session four or five (completers). The two groups slightly differed with regards to marital status (a larger proportion of completers were never married) and how they heard about Step-by-Step (completers being more likely to have heard about Step-by-Step through the internet as opposed to through a friend or family member). See appendix 2 for more information on demographics of completers versus non-starters.

Outcomes of Step-by-Step

Depression as assessed by mean PHQ-8 total scores decreased at each measurement each session among all participants and among those completing post-assessment only, as shown in figures 2 and 3.

Among the 26 people who completed post intervention assessment, the mean number of sessions completed was 4.7. Mean scores on all measures decreased from baseline to post-Step-by-Step, as shown in table 2. There was a significant difference between baseline and post SbS PHQ-8 scores (t=5.62, p=0.00 2 tailed, df=25). An effect size calculation (Hedges' g) estimated the magnitude of that pre-post difference at 1.56 (95% Confidence Interval 1.05-2.07).

The results from the Wilcoxon signed ranks tests showed a significant difference between baseline and post-Step-by-Step scores on all secondary outcome measures (see Table 2).

Figure 2. Mean PHQ-8 scores among those completing each session, from baseline to post-intervention

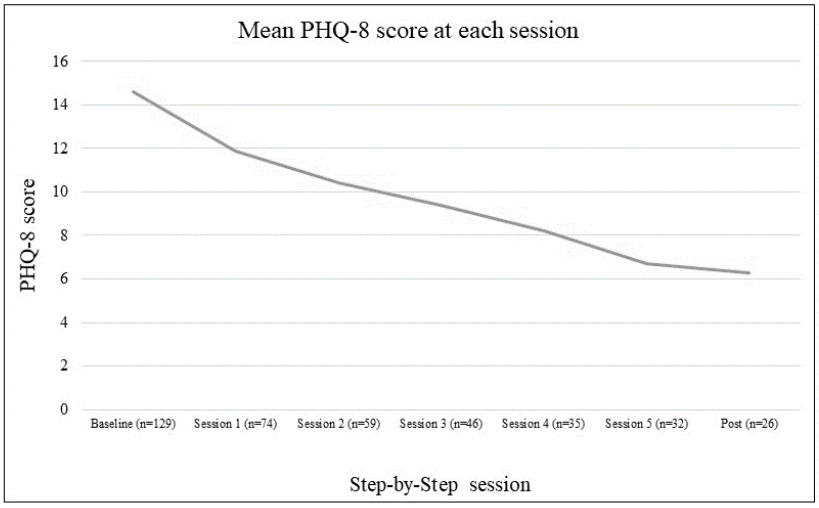


Figure 3. Mean PHQ-8 scores among those completing post assessment only

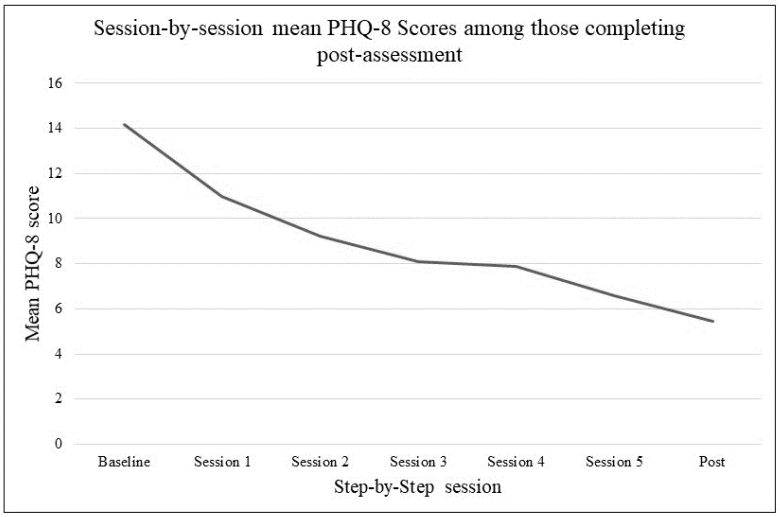


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Table 2. Mean scores, standard deviations and results of Wilcoxen signed ranks test for all outcome measures among participants who completed post-SbS assessment

Measure	**Baseline mean and standard deviation (N=26)**	**Post-SbS mean and standard deviation**	**Post-SbS assessment N**	**Z**	**p**
PHQ-8	13.96 (4.75)	6.31 (5.73)	26	3.903	< 0.001
WHODAS 2.0	15.15 (8.37	9.61 (9.88)	23	2.680	< 0.01
WHO-5	7.96 (3.30)	13.69 (5.19)	23	-3.594	< 0.001
GAD-7	14.11 (4.21)	7.22 (4.31)	23	3.763	< 0.001
PSYCHLOPS	15.85 (3.29)	6.43 (3.98)	21	3.982	< 0.001

Note: PHQ-8 = Patient Health Questionnaire depression scale; WHODAS 2.0 = WHO Disability Assessment
Schedule; WHO-5 = WHO-Five well-being Index; GAD-7 = Generalized Anxiety Disorder scale; PSYCHLOPS =
Psychological Problems and Outcomes, CI = Confidence Interval.

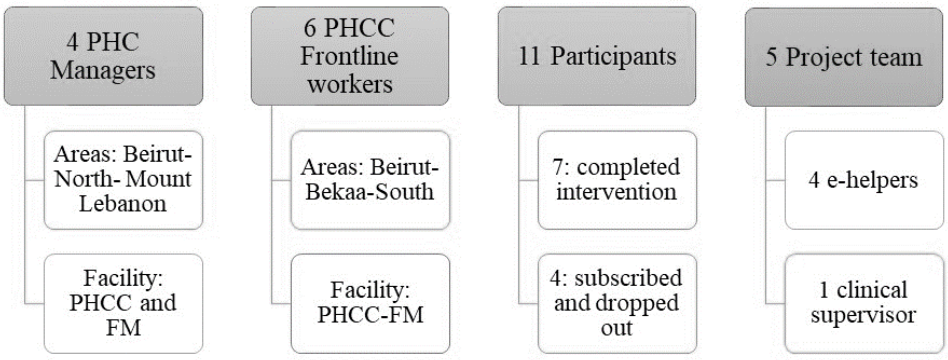
Despite the inclusion criteria to have scored 10 or higher on the PHQ-9 screener (a locally established cut-off, (85), 3/26 did not indicate caseness for mild depression when they completed thePHQ-8 measure at baseline shortly after (a score of 9 or over when using the PHQ-8, Kroenke et al., 2009). Among the remaining 23 participants who had mild to severe depression at baseline according to the PHQ-8, 70% (16/23) scored below the cut off for mild depression at post assessment. Of those who remained above cut off (PHQ-8 > 9) at post-intervention (n=7), three had improved symptom scores, one had not changed and three had slightly deteriorated.

The client satisfaction questionnaire was filled in by 21 participants. Questions used a Likert scale from 1 to 5, with higher values indicating higher satisfaction. Mean item satisfaction for Step-by-Step ranged from 2.9 out of 5 (for the question “to what extent has our program met your needs?”) to 3.8 out of 5 (for the question “If a friend were in need of similar help, would you recommend our program to him or her?). The mean total satisfaction score was 26.5 out of a possible 35 indicating on average these participants indicated high levels of satisfaction.

Process evaluation

The process evaluation consisted of interviews with four clinic managers, six frontline workers, 11 participants (completers or drop-outs), the four e-helpers and the clinical supervisor.

Figure 4. Process evaluation schema.



Results revolved around 5 themes (which were led by the semi-structured interview questions): overall experience, intervention content, rapport with e-helpers, intervention adherence and burden of assessments.

Overall experience
General perception of e-mental health

In general, the SbS intervention was valued and considered innovative among PHCC managers and focal persons, yet, with an acknowledgement that such an intervention needs time to be accepted by the community.

"Even the international visitors were surprised by the posters and were astonished that MoPH is leading on such advanced methods. We need much more time to reach this stage (where people are ready to use it)." (manager)

One manager expressed that she trusted face-to-face therapy only. Most frontline workers and managers agreed that the intervention is more relevant and useful to people of moderate to high SES levels and not to refugees or the disadvantaged population that they serve in their centers. The reasons cited revolved around internet access problems, illiteracy, lack of community knowledge about mental health and the lack of time, financial and human resources to support, follow-up and track patients.

"This intervention could be relevant to people from higher social classes; but at the PHCC level and the refugees' level, it's difficult cause they are mostly illiterate and don't have the concept of caring for their mental health. Maybe better for educated people who are more aware about mental wellbeing."

Their recommendations for service integration were to:

- Ensure a good internet connection;
- Train and allocate assistance for SbS use;
- Conduct awareness sessions frequently and repetitively to spread awareness and normalize use of the intervention.

One frontline worker reflected on the importance of the MoPH endorsing SbS for its credibility, whereas two others expressed their willingness to be more involved and to be given the autonomy to call users and run awareness sessions and workshops by themselves:

"I wish I could be given more authority or responsibility in this, to be able to spread the word in several settings; for example, I can conduct awareness sessions and workshops without getting millions of approvals every time. The system is very bureaucratic here and is obstructing the fast pace of the recruitment in SbS."

Frontline workers reported mixed reactions among clinic users when seeing SbS advertisements: some took pictures and were interested, while others avoided engagement or didn't feel involved. A common finding was that the registration process was complex and inhibited the participation of many. This was echoed in the responses from SbS drop-outs, with their main reasons for not completing SbS being technical and not related to the content of the intervention.

In contrast to these reports, feedback from the seven completers was very positive. SbS was perceived as a feasible solution to physical and financial inaccessibility of services, stigma and isolation, or a great complement to the therapy that some were already receiving:

> *"I am a very busy person and I live far away and don't have access to PHCC. I learned to help myself, I learned new skills to do daily. I knew about it from Facebook and I'm so glad I found it because it benefited me a lot."*

One participant even noted a drastic change in her perception and the self-stigma she had towards mental health:

> *"I was shocked because I didn't want to seem "crazy", yet, when I did it, I understood that having issues does not mean you're crazy and that everyone might be suffering from something eventually."*

The e-helpers all reported to be happy to have taken part, for example, one described the experience as "great, unique and amazing and beneficial". Nevertheless, half of them perceived it as useful to complement face to face therapy.

Recruitment methods could be improved, according to one completer and most e-helpers and focal persons:

> *"The only area of improvement is that you did not advertise for it! I saw it in a clinic and when I went back home, I searched everywhere on the internet and couldn't find it; so I had to go back to the clinic and look for it.*

Intervention content
Story

Both drop-outs and completers liked the story, its pace and length (some did cite that activities were a bit difficult towards the end) and related to the symptoms of the character. Feedback was divided into two: those who were married liked the character profile while those who were not felt that it

was more tailored towards people with families, impeding their ability to relate to the story. They suggested new problems and lifestyles to be added to the story:

> *"I have three kids; I liked the family concept and that it reminded us about the values of the family and the fact that if I get better, my family will be better as well." (drop-out 1)*

> *"I liked the story, it's from the local culture and stems from daily life situations that we are actually living. It would be nice to have more* [suggestions for] *activities." (drop-out 2)*

> *"I could relate to the symptoms but not to the lifestyle; she's a housewife with kids while I'm a student; add examples for younger or older persons (fitting in, peer pressure, university, work)". (completer 1)*

> *"Instead of having the person not wanting to go to work, focus more on a situation where the person still goes to work but feels frustrated, demotivated and irritable." (completer 2)*

They also suggested to change the voice-over in the story video as it was cold and monotonous in many instances. Suggestions were made to use more lively colours and videos in English as well as in Arabic.

Website

In general, all participants mentioned that navigating the site was simple, yet, the log-in process was long and complicated. In fact, three of the four people who dropped out said it was partly due to technical problems or complexity of sign-up.

Rapport with e-helpers

It was noted among participants interviewed and the e-helpers that there was a general preference from the public to have specialist support. Of the four drop-outs that were interviewed, three would have preferred if the e-helpers were qualified specialist therapists. One of the completers also commented on a preference for specialist support.

> *"When the e-helper told me they were not a psychologist, I felt "oups" as I had different expectations; if the e-helpers were experts, their words would have given them more credibility. E-helper was doing the job well but I mean e-helper was not a specialist, so they wouldn't be able to dig more into problems or therapeutic techniques."*

> *"If I were to receive calls, I would have liked for someone professional to call me."*

This was confirmed by the e-helpers who stated that they struggled clarifying to participants that they were not professionals, especially to those who expected to get professional support.

> *"The concept of self-help is new which could explain their expectations"* (e-helper)

Having said this, the three that had contact with an e-helper all commented very positively on their relationship with the e-helper and found the support positive and helpful.

> *"I used to wait eagerly for Monday calls to let it out in a healthy way instead of hitting my children. So really this was very helpful."*

> *"I didn't feel she was a therapist, rather, she cared as a friend and wanted to make me feel better; she was compassionate. I loved it. She made me feel alive and that I exist".*

> *"I think that's what makes the program very special. It gives you motivation- it makes it more personal"*

From the e-helpers' perspective, they described their rapport with the participants as very diverse and classified the users into four groups: the active and responsive users, who benefited the most from the program; the inactive yet responsive users, who received support without doing the sessions; the active yet unresponsive users, who did the sessions independently and did not wish to have support from e-helpers; and those who were both inactive and unresponsive after sign up.

In addition to the above, e-helpers shared some challenges encountered while dealing with special cases such as users who got attached to them, asked them personal questions or were high risk cases (mainly presenting with suicidal ideation).

> *"Some asked me "do you love me?" others inquired about my personal information "family name, age, religion, area of origin" and one or two asked for a meet up with some of us" (e-helper)*

The main recommendations regarding e-helper support were to:

- Focus more on the suicide risk management procedure in the training;
- Add more self-care techniques for the e-helpers who are susceptible to stress or burnout;
- Lengthen the shift times of the e-helpers in order to ensure cover of busy afternoon hours;
- Add notifications and reminders for participants to comply with the intervention

All these recommendations were taken into consideration by the project team in planning the next phase of the project.

Intervention adherence

Problems with reminders and motivation were prevalent among participants whereby most forgot to log-in, practice their activities and respond to the e-helpers' messages/calls. Recommendations were made to make the website more interactive and dynamic. Two completers suggested to add push notifications and empowering messages, including praise and potentially personalized motivational messages.

E-helpers affirmed these findings by stating that they were frustrated with following up and reminding the unresponsive or the inactive users to log in, attend their support sessions or do their sessions and activities. They also recommended to add pop up notifications and reminders prior to the support sessions, and whenever a new session is available.

One drop-out stated that she lacked the motivation and time to practice the activities which added more stress on her:

> *"When I saw this program, I thought to myself: "that's it! This is what's missing in my life and I've got to do it!" but then I lacked motivation…I don't have a minute to calm down and I usually stay late at work. So when I come back home, I stop doing anything- and I stress out for not being able to do the activities that I wrote. I need a break but I can't do anything else, which makes me hate myself."*

Website user behaviour and preferences

A total of 4209 unique visitors came to the site during the recruitment period, including study staff. Most people accessed the website using smartphones (62%), followed by computers (26.5%) and other devices such as tablets (12%). At sign up, participants most commonly chose to communicate to e-helpers by email or WhatsApp messaging (n=74 or 57.4%), then by phone (n=32 or 24.8%), and then by using the instant message "Chat" function within the website (n=23 or 17.8%).

The analysis of web traffic provided limited but some relevant information including when there were peaks in the number of site visits, which coincided with Facebook advertising drives (December 2017 and February 2018). It also showed that between 23% and 32% of website visitors were lost at the point of screening. Between 53% (English website) and 69% (Arabic website) of people who did complete the screening repeated it if they were excluded. The web analytics showed that just 19% of the visitors (on the Arabic and English website) clicked on the detailed study information. Participants who watched the videos of the sessions watched between 21% and 75% of the video length on average.

Discussion

The data from this uncontrolled pilot test (completers n = 26) showed mean depression symptom scores to decrease at each time point throughout the intervention among those who continued the intervention. Despite a substantial attrition between baseline and post-intervention testing, session data seemingly showed symptoms to improve. Pre- and post-intervention data showed a statistically significant reduction in symptoms of depression and anxiety, improvement in wellbeing and in functioning and a reduction in the magnitude of self-defined problems pre- and post-Step-by-Step. Though the effect size calculation on depression scores should be taken with caution due to few participants and no control group, its magnitude was significant, at g=1.56 (95% Confidence Interval 1.05-2.07). The uncontrolled study design and lack of post-intervention data from drop-outs means that one cannot rule out natural recovery or other extraneous variables causing this effect. Qualitative data gathered through process evaluation interviews with a number of stakeholders suggest that the intervention itself is acceptable and feasible and that motivation and/or technical problems were key reasons for drop-out, as opposed to intervention content or the general concept of the delivery model. This research shows that there are a number of considerations to incorporate into the intervention itself and into the design of further effectiveness testing.

Disproportionately few people who signed up to this study were Syrian or Palestinian. The social media campaign was limited to advertising through the MoPH Facebook pages, so was more likely to

have attracted nationals who have an interest in health. Furthermore, Whatsapp advertising was limited to two university student groups, attracting younger, more affluent Lebanese students (as Syrians and Palestinians in Lebanon are less likely to go to university than Lebanese nationals). Further testing of SbS will focus more on recruiting Syrians and Palestinians as well as Lebanese people, weighing more heavily on using social media to capture potential participant's attention. An important learning point was that recruitment materials should be tailored for different population groups and should use a broader range of social media channels. The research team is currently also considering linking to international organizations and NGOs that serve Syrian refugees specifically for recruitment support.

The results from this pilot study are informing an updated smartphone app and website version (hybrid) of SbS, which will include offline capabilities and features such as notifications and a within app communication channel for support. Demographic data and user feedback has also informed content changes (making SbS more tailored to unmarried, economically active users). It is expected that the new app version will address the many comments gathered in the interviews, making it easier to use more equitable with regards to data costs for participants. Planning has started for the next phase of testing, with much more reliance on social media and other digital channels for recruitment and also calling on partner agencies, service providers and other community resources to attract potential participants.

Though the primary effect size calculation found in this study is likely overestimated due to design limitations, it (Hedges g = 1.56) is comparative to the effect sizes shown in other studies which used guided e-mental health in the treatment of depression in high income settings (21), effect size= 0.98;(22)(23). Forthcoming RCTs will shed more light on SbS effectiveness compared to like interventions.

As an uncontrolled pilot, this study carries a number of limitations. Of the 129 people that were recruited, those completing four sessions or 80% of the intervention (considered an completer) were 35 (27%) and those completing post assessment were only 26 (20%). These figures are high compared to other e-mental health studies, which often have rates of attrition at around 33% ((43)). 41% of those who signed up did not commence SbS (also a problem in other e-mental health studies, for example, Watts et al 2013, where 33% were lost at sign-up (93). With so few participants providing both baseline and post-intervention data and without a control group, the findings should be interpreted with caution and considered only as an indication that the intervention might be efficacious. Further testing is planned for 2019 and 2020, during which we will focus recruitment activities on the seemingly more effective method of advertising on social media, additionally targeting Syrian refugees through refugee- dedicated services.

Web analytics data showed that a number of participants re-entered data presumably in order to get access to SbS after they had been excluded. This presumption is supported by the fact that 3/26 participants who completed baseline and post-SbS assessments did not indicate caseness for mild depression when they completed thePHQ-8 measure at baseline shortly after they were indicated for caseness at screening. During further testing, it will be important that website visitors cannot re-enter screening information once they have been excluded from the study.

We cannot be sure from the data gathered in the process evaluation why there was such a high number of non-starters (41%), incremental drop-out and people who did not complete the post-assessment, though motivation was commonly mentioned by the participants we gathered feedback from. Participants were sent up to three email reminders when they did not log into the system and when their post-assessment was due. E-helpers also tried to call (up to three attempts) those who provided their phone number to remind them of the post-assessment. It seems from formative work carried out that email is not the best means of communication with the target user group as email addresses or login details are often forgotten. E-helpers recalled that the success rate (number of call attempts versus number of calls answered) of the reminder calls for post-assessment was low.

Though "non-use" attrition (i.e. people registering but never using the intervention) is not unusual in mental health interventions, we gathered anecdotal knowledge that professionals (e.g. academics, health staff and NGO staff) had signed up to the intervention out of curiosity having seen social media posts or hearing about it through colleagues. Furthermore, analytics data suggested that some users who were excluded re-submitted answers to the screener, meaning that people for whom the intervention was not designed were signing up. For example, people not suffering from depression, people having suicidal thoughts, therefore needing more targeted support or those not intending to use the intervention may have registered for SbS. This was a very important learning point and for the app version of Step-by-Step, we will need to make a separate discovery area or resources for people curious about Step-by-Step. Finally, one of the completers we interviewed for the process evaluation said they were also receiving concurrent face-to-face therapy. Participants for whom this is the case should be flagged in future trials for analysis purposes.

Pilot and feasibility studies aim at identifying potential problems and solutions before running large trials and the lessons learned during this small pilot test are important. It will be necessary to make the intervention much more user-friendly, to enhance recruitment methods (particularly to recruit Syrians, as numbers were so low), to ensure more training for e-helpers on suicide case management, increase motivational content and review the story to make it more relevant to single users. The app version of the intervention will be more attractive and engaging and user-friendly. Evidence indicates that attrition rates are lower in highly interactive e-interventions (44,78,94), and although more evidence is needed on this particular question, we envisage that the ease of use, ability to send participants motivational notifications directly to smartphones, and the offline capabilities of an app may reduce attrition rates.

Conclusion

The Step-by-Step e-mental health intervention has feasibly resulted in reductions in symptoms of depression and anxiety among those who completed the intervention, though the study was uncontrolled and sample size was very small. Completers also indicated a reduction in disability and perceived life problems along with an increase in wellbeing. The quantitative results, as well as the qualitative process evaluation and responses to a client satisfaction questionnaire provide support for the potential of the intervention to help people living in Lebanon, however, it is essential to make

some content and procedural adaptations to the app version of the intervention ahead of randomized testing in the coming year. This form of treatment could, in the future, increase capacity to provide care to people living in Lebanon via the internet who would otherwise not have access to evidence-based care.

Supplementary material

Supplementary material 1. Process evaluation semi-structured interview guide for participants of the intervention.

Semi-structured qualitative interviews conducted after the e-mental health intervention pilot intervention

Key informant interviews will last up to one hour, and will follow the following semi-structured interview guide. Informed consent will be obtained immediately prior to interviews (Consent form at the end of this document)). Interviews will be conducted no longer than 6 weeks after the conduct of final outcome assessments. In the case of users, interviews may take place over the phone and thus consent will be taken orally in that case.

All key informant data will be recorded, main points translated, and analyzed following inductive thematic analysis. Findings from this phase of the study will be used to further refine intervention delivery to the local context where required, and to inform the future proposed RCTs of intervention effectiveness.

Part 1. Interview Guide: Intervention Participants

1. Greet person. Introduce self, including what organization you are working for. Explain the study following written informed consent process (Consent form at the end of this document)). Possible additional explanation of semi-structured interview process:

   We would like to ask you some questions about your experience of the internet-based programme that you used, to help us to think about how it could be improved in the future. There are no right or wrong answers to the questions we are going to ask. The interview will be recorded without any identifier to make sure that answers are transcribed accurately; all answers will be reported anonymously to ensure confidentiality. We will be speaking to a number of people, asking everyone the same questions. If you feel unable to answer a question please say and we will move on to the next one.

2. In note book document date and site of interview, age and gender of interviewee, their position but not their name (i.e. intervention participant, helper, Head of clinic), and initials of interviewers.

3. Begin semi-structured interview:

Record responses and make pertinent notes in the notebook.

Interview process:

- Overall impressions:
  - *1- Please describe your experience of the internet-based programme that you used*
    - Explore positive / negative views through probes.
- Intervention:
  - *2- Describe that we will be making an app for the next phase. Ask the participant to think back to their experience of using the website and ask for suggestions for the app, including features. (any feature or function you would like us to change or add in the app? Any recommendations for colors, etc..)*
  - *3- What did you think of the story? (probe if needed: how did you feel about its relevance, Redundancy, difficulty, Motivational...)*
  - *4- What did you think of the audio exercises? (probe if needed: voice, pace, difficulty, effectiveness)*
    - *What could be improved?*
  - *5- What did you think of the interactive activities?*
    - *What could be improved?*
- Rapport with helper:
  - *6- Please describe how you found working with your helper*
    - Explore positive / negative views through probes.
  - 7- How did your family view calls you received or your relationship with your helper?
    Explore positive / negative views through probes.
  - *8- How could we improve the contact methods, for example the timings or how we contact users?*
    - Explore further if they are not clear.
- Intervention adherence:
  - *9- Please describe how easy or difficult you found it to complete the five sessions*
    - Explore barriers and facilitators to attendance.
    - Frequency of sessions, length, video vs slides
  - *10- Please describe how you found implementing the skills the helper taught to you in your everyday routine*
    - Explore barriers and facilitators to skills development.
  - *11- How could we encourage users to use SbS as intended e.g. reading the story, watching video, or filling in the activities boxes?*
  - *12- Is there anything else we could do to help users stay motivated?*

- Explore further if they are not clear.

- <u>Burden of assessments:</u>
  - *13- Please describe how easy or difficult you found doing all the assessments, consenting and registration for this research*

4. Review any written records with the interviewee still present. If anything is not clear ask for clarification and correct written notes as necessary.

5. Ask the interviewee if they have anything to add. Any additional information is added to the interview notes as required.

6. Thank person and leave.

Supplementary material 2. Table showing characteristics of non-starters versus characteristics of completers.

Characteristic	**Non-starters (n=53)**	**Completers (n=35)**
Mean age	27 years old	28 years old
Mean pre-SbS PHQ-8 score	14.9	14.7
Female	81%	77%
Nationality		
Lebanese	89%	89%
Palestinian	4%	3%
Syrian	4%	6%
Other	4%	3%
Education level		
Primary school (3-6y)	0	0
Elementary (6-14y)	4%	0
Secondary school (15-17y)	6%	9%
18+ years	83%	91%
Occupation status		
In work	40%	29%
Student	26%	34%
Homemaker	15%	9%
Unemployed	13%	20%
Other	4%	6%
Location		
Beirut	42%	40%
Outside Beirut	45%	57%
Outside Lebanon	13	0
No answer	0	3%
Marital status		
Never married	49%	66%
Currently married	34%	26%
Separated/divorced	4%	9%
Widowed	2%	0
How did you hear about SbS?		
Friend/family	34%	14%
Health worker	8%	3%
Poster/flyer	8%	9%
Internet	58%	69%

Conflict of Interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Author Contributions

SW, MHS, EvH, KC and MvO designed the intervention, with the support of JAR, REC, EZ and WK for local translation and adaptation. EH and AW were responsible for creating and managing the website. MHS, JAR and CK designed and conducted the study with the support of PC, REC, EH, WK, KS, MvO, EvH, AW and EZ. MHS, JAR and PC analyzed the data and all other authors contributed to the interpretation of the data. MHS and JAR wrote the manuscript and all authors carefully reviewed the manuscript and gave final approval of the work to be published.

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List of Abbreviations

SbS Step-bs-Step

MoPH Ministry of Public Health, Lebanon

PHCC Primary Health Care Center

WHO World Health Organization

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Data Availability Statement

The datasets generated for this study are available on request to the corresponding author.

Chapter 8:

Methodological contributions

Methodological contributions

This chapter includes my methodological contributions to the thesis work, written in the first person, in order to provide the reader with an idea of my exact role. Please find also further reporting on methodological reflections and lessons learned during the PhD in appendix 3.

Contribution to the qualitative analysis of PSYCHLOPS data (chapter 3)

I was first and corresponding author of this article and my role included managing the thematic data analysis, write-up and peer review process. The data that formed the basis of this article was from two large trials carried out by WHO and partners in 2014 and 2015. With regards to the Pakistan trial, my role was ethical review committee (ERC) liaison person[5] and donor reporting assistance. My role on the Kenya trial included ethical review committee liaison person but additionally co-authoring the study SOPs and running a weekly project monitoring conference call to ensure that SOPs were being followed in a timely manner.

Contribution to the systematic review on cultural adaptation of self-help and minimally guided interventions (chapter 4)

As first and corresponding author of this paper, I conceptualised and managed the research from start to finish, as well as writing up the manuscript and managing the peer review process. I undertook the systematic searching of major medical databases, extracted articles and data, ran a meta-analysis and meta-regression with the guidance of my supervisor, assessed the quality of the articles retrieved and also designed and managed the methodological questionnaire (for retrieved study authors) and its responses. My co-author EH was the second rater in terms of article selection, data extraction and quality assessment, as well as reviewing the manuscript.

Contribution to the pilot e-mental health project in Lebanon (chapters 5 to 7)

The WHO research strategy on low intensity psychological interventions research follows the guidance laid out in the UK MRC Framework for the Development of Complex Interventions (74), which recommends piloting studies prior to large scale RCTs to address intervention and research design limitations. As part of my PhD work, I managed the process of intervention development and the initial feasibility and piloting phases of the WHO's e-mental health for depression project in Lebanon (Step-by-Step).

[5] My role at WHO between 2014 and 2018 included being the ethics focal point for many of the research projects being carried out by my team. This role included writing or supporting my colleagues to write ethics protocols and annual reports, attending ethics committee meetings and reporting adverse events to the committee. For the purpose of this thesis, I summarise this role as "ethical review committee liaison".

Throughout the PhD, my role in the project was substantial, including co-authoring and contributing to the funding proposals for this and future phases of the project. In close collaboration with clinical psychologists and the local team in Lebanon, we designed Step-by-Step (see chapter 5). I was responsible for the day to day running of the project, including running annual project planning meetings in Lebanon, managing contractors and donor relations. My Lebanon-based colleague JAR conducted and analysed the data for the qualitative elements of the thesis research (in Arabic), with my close supervision. There were three main phases of the project during my time: intervention design; contextual adaptation; and pilot research. Further methodological insights are illustrated in the following sections.

Intervention design (chapter 4)

Intervention design started with a literature search, expert interviews and subsequently, a concept note. The concept note was then peer reviewed and major edits made to the intervention. An illustrator was hired and detailed illustration briefs were provided. The website programming was carried out by the University of Zurich and required close collaboration by weekly conference call to monitor progress and to check for bugs in the website before it was launched.

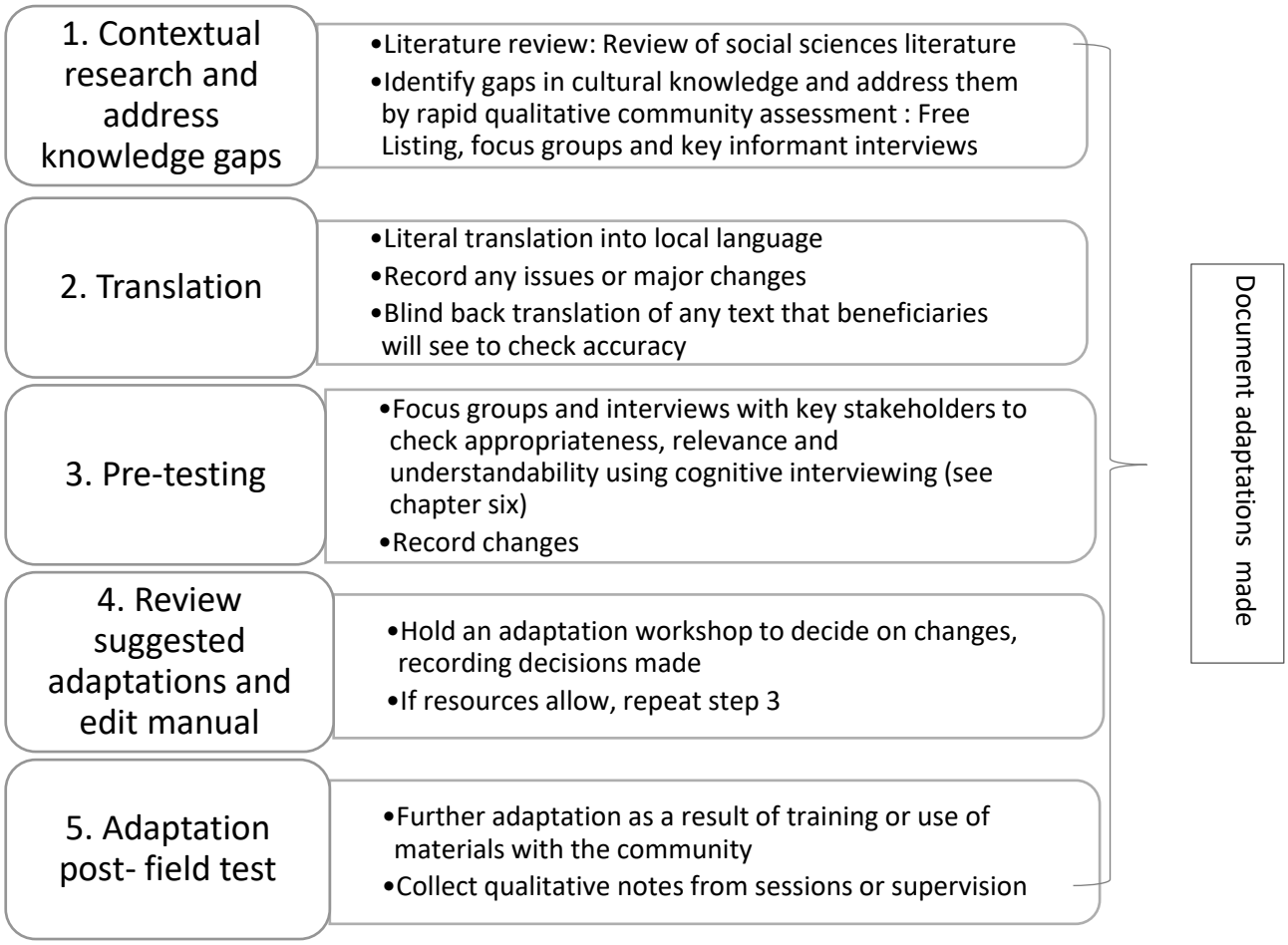
Translation and cultural adaptation of the intervention (chapter 5)

One of the first steps of cultural adaptation (after any desk reviews of the local culture and preliminary community assessment) is translation. During translation, we paid attention to conceptual equivalence and not only to linguistic equivalence. This means making sure that not only the words are translated, but that the concepts of the text remain meaningful. Forward translation into classical Arabic was carried out by a person sharing the same mother tongue as the target population. (Preferably this person should have some mental health knowledge or experience.) Two further Lebanese team members then revised the classical Arabic translation into spoken dialect appropriate for Syrians, Palestinians and Lebanese people. The final translation of the intervention was in non-technical and possibly colloquial language so that local people could understand it. Translation took time, if some areas of text could be particularly difficult, so in the future to facilitate the process, translating and checking the language on some concepts ahead of full translation could be useful.

The cultural adaptation research took place across Lebanon in autumn 2016. We used lessons learned through interviews with colleagues who had adapted other WHO psychological interventions in Kenya, Pakistan and Uganda in order to design an efficient translation and adaptation procedure. In Lebanon it was not necessary to conduct a local review or community assessment, as the local team included psychologists and psychiatrists who were already very knowledgeable about the context. In Lebanon, we started with translation. Using interview/focus group schedules for the Lebanon adaptation research and working closely together, my local counterpart JAR and an assistant collected the data. Once the data were gathered, it was translated into English and presented by JAR during an adaptation workshop. During this meeting, the team made the final decisions on what adaptations to carry out while preserving the original therapeutic elements of the intervention. I then edited the intervention in line with the decisions made and sent it back to the MoPH team for translation. The process was supervised by a clinical psychologist at WHO headquarters (KC). This process and the results of the qualitative research were written up by JAR and myself in a paper that was published in 2018 (see chapter 6). Shortly afterwards, a team in

Macau who are also adapting and testing Step-by-Step for Philipino migrant workers commenced their qualitative research. I assisted them in designing their adaptation research based upon our experiences in Lebanon.

Figure 2. Flow diagram of the suggested process of adaptation based on lessons learned from adaptation of PM+ and SH+ in Kenya, Uganda and Pakistan.



Step-by-Step feasibility testing (chapter 7)

In keeping with the UK Medical Research Council guidance mentioned above and having had the initial project planning meeting (in which a range of Lebanese stakeholders took part) where formative phases were planned, we designed the pilot research with questions around future RCT methodology in mind. Such questions included whether an "e-helper" minimally guided model would be accepted in Lebanon, who and how many e-helpers were necessary, how we could recruit a representative sample of people residing in Lebanon, whether participants would engage with Step-by-Step etc. The pilot study had an uncontrolled, pre-post design with a qualitative process evaluation in order to answer our questions about research methods.

Once the team was clearer about the research design, supervised by KC and with inputs from other team members, I wrote a draft ethics proposal and Standard Operating Procedures (SOPs). A major ethical conundrum that we faced concerned participants who present with suicidal thoughts or

plans, which presumably is the case with many mental health research trials in LMIC. In Lebanon at the time, there were no services specifically for suicidal people and barely any trained health workers to assist suicidal people. There was only one service that didn't incur high out of pocket care costs (typically admission to an inpatient psychiatric facility), which was an emergency response (ambulance service) from the Lebanese Red Cross, and that was already overstretched and struggled to reach rural areas at all. The MoPH at the time were in the process of training emergency room and PHCC staff and, in collaboration with a local NGO, were setting up a national suicide helpline. We had originally envisaged an on-call psychiatrist hired especially for the trial, but upon scrutiny from the WHO ERC, we realised that the plan was unfeasible and that the privacy of participants was at risk. Having put the project on hold until the MoPH had set up the helpline and trained health staff cross the country on management of suicidal behaviours, the ERC accepted that we screen suicidal people out of the study upon sign up (as is common in e-mental health research). They accepted that should anyone become suicidal, they be referred to their nearest trained practitioner and the suicide helpline and that they receive extra telephone support from study staff (if they accept it) until they were deemed less at risk. This meant that suicidal people would not have access to the intervention, which we deemed ourselves unethical given that this group is often excluded from mental health research trials, but the ERC considered this work around acceptable.

Other ethical issues highlighted by the ERC included general practitioners recruiting participants (potentially introducing a passive pressure on patients to sign up), and recruitment at PHCCs potentially stigmatising potential participants if recruitment efforts were overt, so remote online self-sign up was used. The ERC was also concerned that we needed to confirm that we had sufficient funds to cover any necessary acute care costs of participants during the study.

The ethics proposal and SOPs were finalised through a second project planning meeting in Beirut, and JAR carried out other formative work in Lebanon ahead of the feasibility test, such as ensuring the PHCCs that would have recruitment posters and leaflets had internet connection should participants want to use wifi there for free (so getting them tablets and 4G modems). With the support of the team at WHO headquarters, the local team recruited the e-helpers, translated and tested the website and other preparatory tasks. My colleague KC and I went to Lebanon to train the e-helpers. This training covered mental health, technical training on using the website, counselling skills and dealing with challenging situations/clinical presentations.

The data for the feasibility pilot test was collected automatically via the Step-by-Step website and I exported this date to Excel, and then to Stata (version 14) for analysis. Web analytics were compiled by AW, the website programmer, and effect size calculations were computed by our colleague PC using Comprehensive Meta-Analysis (Version 3.3.070). JAR conducted most of the process evaluation interviews and analysed, compiled and translated the data for me to write up in the manuscript with her review. See chapter 7 for the submitted publication of the pilot feasibility test. The experience and results from this stage have impacted heavily on the plans and research methods of the currently ongoing project phase, the controlled pilot study and the forthcoming fully powered RCT.

Chapter 9:

Discussion

Discussion

Key findings

Chapter 3 key findings: Using PSYCHLOPS in Kenya and Pakistan

This study constituted the largest data set of PSYCHLOPS ever published. In both Kenya and Pakistan, the responses to the PSYCHLOPS PGOM gave rise to problems that were not found in the nomothetics used as outcome measures in the two efficacy trials. Furthermore, the problems cited were different in both of the settings. For example, people in Pakistan did not cite unemployment as a life problem and rarely mentioned finances, whereas in Kenya, financial difficulty was the most frequent problem cited, with unemployment also very common. In Pakistan, they cited emotional or psychological problems (sadness and importantly, anger or irritation) much more frequently than Kenyan participants did. A relatively large proportion of Pakistani participants cited headaches as a major life problem (perhaps as an idiom of mental distress), but this was rarely cited in Kenya. These diverging results, both between sites and in comparison to nomothetic measures of common mental disorders, show that asking participants about their self-perceived problems brings additional insight about the values of participants in mental health research. For further discussion of the interpretation of the results found, see chapter three.

Chapter 4 key findings: Cultural adaptation of self-help interventions, meta-analysis

The systematic review carried out on self-help interventions showed that published research does not include enough detail about the adaptation processes used. This prevents replications, reduces transparency, and limits clear understanding of methodologies used. Of the 3886 studied screened for inclusion, we included eight randomised controlled trials studies of self-help interventions in the meta-analysis (four on e-mental health interventions and four on bibliotherapy). The pooled standardised mean difference (effect size) of the interventions from retrieved studies was -0.81 (95% CI -0.10 to -0.62) in favour of the active intervention compared to a control, with low to moderate heterogeneity between the studies (I^2=28.9%, p=0.188). Using the assigned adaptation score of each study in the meta-regression we found that a one-point increase in the adaptation score of a study was significantly associated with an increase in standardised mean difference of 0.117 (p=0.04).

Chapter 5 key findings: Designing a scalable e-mental health intervention

Step-by-Step was created as a five session, behavioural activation intervention for depression that is delivered through smartphones, tablets or computers. Self-report outcome measures are incorporated into the intervention after sign-up and after completion. It uses the story of a person who suffers depression symptoms and gets help to relieve their symptoms, with interactive activities to enable users to integrate strategies into their own life. Step-by-step was designed to be delivered with the option of a non-specialist support person to accompany the user through the intervention via up to 15 minutes phone or text-based support sessions. Other implementation considerations were incorporated, such as open-source software and vector graphics to illustrate the story for easy of widespread use in the future.

Chapter 6 key findings: Cultural adaptation of Step-by-Step in Lebanon and Macau

Using a bottom-up community driven approach, we adapted Step-by-Step for Lebanon (general population) and for Macau (specifically for Pilipino migrant workers). Using key informant interviews with health workers and focus groups (followed by key informant interviews where necessary) with community members, we gathered data on the acceptability, comprehensibility and relevance of the intervention content.

Example contextual and cultural adaptations can be found in Table 3. More details can be found in chapter six.

Table 3. Examples of cultural and contextual adaptations made to Step-by-Step in two settings.

	Lebanon	Macau
Acceptability	A doctor was the wise character who imparted the therapeutic content to the story-telling character (a doctor is very trusted figure in Lebanon) and their tone should be prescriptive and direct.	A respected elder was providing therapeutic content to the story-telling character (a doctor was deemed pathologising and stigmatising).
	Hand gestures and some background colours changed because they were associated with a particular political party.	Hand gestures and reference to illicit drugs associated with a particular political party/the current president's war on drugs.
	Rest emphasised as a positive coping strategy due to fast pace of life in Lebanon.	Negative coping and coping behaviours modified e.g., for migrant domestic workers, staying in bed is restorative not a negative strategy.
	Illustrations of males in distress were made more masculine, e.g., head in hands as opposed to crying.	Illustrations of males in distress were made more masculine, e.g., head in hands as opposed to crying.
	Make videos/voice overs so less reading is required.	Change intervention goal from helping to better cope with difficult emotions, to helping to become a better overseas worker for the family's sake. This is less pathologising and more focused to the life goals of Philipinos in Macau.
	'Satisfaction' in Arabic had sexual connotations so it was replaced by 'feeling of joy or peace'.	
Relevance	Names of characters needed to be relevant to all religious groups.	Selected names were meaningful in Philipino, e.g., wise-person or fighter

		and were modern for younger characters.
	Male and female characters as parents and female as a homemaker is not relevant to all users.	Characters wore simple clothes but with jewellery to show status so that users would want to be like them.
	In Lebanon, wives and husbands prefer to talk to friends about their problems, rather than to each other.	Warmth and hospitality are important, so the tone of the story was made more personal.
	Problems in the story were updated to include financial problems, work stress and violence and conflict.	Problems in the story were updated to include missing their family, conflicts with peers and employers and needing a break from working hard.
	Some activities were revised., e.g., going for a walk alone is not an option for some Syrian women, or playing with children was not deemed a restorative activity. Listen to favourite singer was changed to favourite music as in some religious sub-groups, music is restricted to instrumental and traditional music.	Activities were revised to include low-cost and not too time consuming activities like eating mereinda, videoke and visiting sites in Macau. We excluded unfeasible or unfulfilling activities like gardening.
	Some activities remained gendered despite trying to make them gender neutral, as some activities are considered typically male or female in Lebanon e.g., women cooking and men going to a café to play board games.	
Comprehensibility	Intervention in both Arabic and English as many younger participants use apps and speak in English with peers.	Intervention in both Tagalog and English as many younger participants use apps and speak in English with peers.
	Some sentences were made shorter and simpler.	Some sentences were made shorter and simpler.
	Remove repetition and cut the length of the story by at least one third as people don't like to read a lot of text.	Remove repetition.
	Change simple coping strategy of drinking a cup of tea as some misunderstood that	

	the tea was a herbal treatment for depression.
	"Tired psyche" was used as a local idiom of distress, with less focus on inactivity as a symptom.

Chapter 7 key findings: Feasibility testing of Step-by-Step

This uncontrolled feasibility test found that completing Step-by-Step lead to statistically significant changes in depression and anxiety symptoms using the PHQ-8 and the GAD-7. It increased wellbeing (WHO-5) and functioning (WHODAS) and decreased the magnitude of self-perceived problems (PSYCHLOPS) scores. Overall, the intervention was accepted and process evaluation interviews with users, drop-outs and other key stakeholders provided a number of insights which will impact future testing and use of Step-by-Step. For example, to avoid cited technical problems, an app will be made to replace delivery through a website. Process evaluation showed that three of the four drop-outs interviewed dropped out partly because the website was not easy to use. Adherence was a major issue in this feasibility test phase and many participants interviewed cited motivation issues and forgetting to log in, which could potentially be remedied by push notifications on an app (optional, to protect the privacy of those using a shared phone). Younger, single users mentioned that they found it hard to relate to the story because the main character had a different family and occupational status to them. Recruitment was a major challenge, so future recruitment for subsequent studies will be more focused on sub-groups of users and through wider social media channels. It is important to note that the study was uncontrolled, and the sample size was very small, so further, controlled and fully powered testing is currently being undertaken.

Comparisons with other studies and contextualization

In comparing our findings from using the PSYCHLOPS in Kenya and Pakistan to similar studies in the UK (95–97), some of the main problem categories are similar, with exception to UK listed problems around self-esteem, sex and sexuality, psychiatric diagnostic or clinical labels, and past loss or trauma. The nomothetic measures used alongside the PSYCHLOPS didn't cover all of the problems cited in response to the PSYCHLOPS. With regards to our finding that adaptation of self-help interventions increases efficacy, our results are consistent with some evidence from previous systematic reviews on the cultural adaptation of face-to-face interventions for common mental disorders (62,63,98) but are inconsistent with one other high-quality meta-analysis (28). While there are a number of meta-analyses on the effectiveness of adapted interventions, the meta-analyses or their constituent articles rarely cover in detail the methods of adaptation. One meta-analysis identified only 8/20 studies that detailed their methods of adaptation sufficiently, and 6/20 studies that involved community members in the adaptation process (the remainder using local health workers or specialist researchers or clinicians) (62). In chapter 5, we involved community members as well as health professionals and service managers as informants. The two published studies of the Step-by-Step adaptation process (chapter 5) are the most detailed published accounts of adaptation

methodologies that we are aware of, alongside the recent adaptation of an e-behavioural activation intervention in Colombia (99).

The pilot study of Step-by-Step is relevant and timely, as there is no literature on the use of a minimally guided e-mental health intervention for depression in Lebanon and just one account of e-mental health being used in the Middle-East for post-traumatic stress disorder (PTSD) (100). Searching for literature on e-mental health in LMIC reveals published studies on e-mental health for PTSD (101), and addiction (102) in China; one on anxiety (103) and one on depression in Romania (104); and an attempted e-mental health intervention study for depression in South Africa (105). There are ongoing studies for internet-delivered behavioural activation interventions for depression in Indonesia (106) and in Colombia (99). In running the first uncontrolled pilot of Step-by-Step in Lebanon, a major issue was that 41% of users who signed up to the intervention did not start, and just over half of those that did, did not complete the intervention. This attrition rate is higher than that estimated by meta-analysis of e-mental health intervention adherence and attrition rates in European, Australian and North American studies (43), and is worrying ahead of further research on Step-by-Step. Because of these study limitations, comparison to other LMIC studies at this stage is not warranted.

Clinical and policy implications

This thesis has showed that a PGOM can be used as an inlet to therapeutic discussion (as part of a problem solving intervention, but it could also be used as part of other therapies) to ensure that the person's problems and their values are addressed in therapy. It may also be used as a monitoring tool to track the progress of therapy in terms of its effect on the clients self-perceived life problems, and to evaluate the success of the intervention alongside a nomothetic outcome measurement tool. Importantly, asking community members about the key problems in their lives could be an important step in formative research before implementing mental health interventions. It may be necessary to tailor the selection of therapies and their content to local problems and treatment goals.

Both clinically and at the policy level, this thesis carries the important message that adaptation of an intervention to the target population may increase the effectiveness of the intervention substantially if it is carried out comprehensively. At public health scale, the cost-benefit of carrying out adaptation could be very interesting to decision makers. Given that adaptation is a one-off exercise, and that our findings showed a positive association between adaptation and efficacy of an intervention, this process could be worthwhile, though further investigation into the mechanism of this increase in efficacy is warranted.

Additionally, at the community level, inviting members of the community and health care workers to be part of the formative research of an intervention may increase the local buy-in. This could be helpful to implementers of a similar intervention, especially given that we found some stakeholders to be dubious about innovative delivery methods of psychological interventions. Involvement and acceptance by community members, as well as advertising this involvement in dissemination materials could increase the perceived legitimacy of an intervention, leading to further uptake.

In clearly reporting our adaptation methods and results, we hope that teams potentially tasked with adapting evidence-based interventions in other parts of the world may be able to use and adapt our

method to their setting in order to achieve adaptation themselves. This, in addition to the finding that adaptation increases effectiveness, may enable service planners a more informed decision as to whether to invest in adapting an intervention or not.

Though this feasibility test was based on a very small sample size and high drop-out, Step-by-Step was found to have a positive effect on the mental health of the participants who completed the programme. Innovation in delivery of psychological interventions, such as self-help or guided delivery models using bibliotherapy or e-health could increase the reach of evidence based interventions to people in need. Careful consideration when designing such an intervention should be taken, to ensure the end product is feasible for a health system to integrate into existing services and maintain at minimal cost. Providing care through the internet particularly could lift a range of barriers to accessing face-to-face care, such as stigma, geographical constraints, security threats and face-to-face care costs. More countries should include e-delivery as a strategy in policies and planning for national-level mental health care, potentially as part of a stepped-care approach, taking the pressure off specialist care services which are not able to serve all in need.

Suggestions for future research

The limitations of the research carried out have been detailed in chapters 3-7. In order to overcome these limitations and increase the knowledge base in person-centred measurement and monitoring and adaptation of and app-delivery of psychological therapies, a number of future research recommendations can be made.

Using the PSYCHLOPS posed some methodological problems, so its use would require clear instructions. The PSYCHLOPS data from Kenya and Pakistan, or indeed from elsewhere, could be analysed quantitatively to ascertain further the added value in using it as an outcome measure. This could consist of comparative psychometric analysis of the data with data from nomothetic instruments and an analysis of the measure's sensitivity to change, validity and consistency.

In terms of understanding the link between cultural and contextual adaptation, some questions remain unanswered. Because this meta-analysis did not pool the results of studies comparing the same intervention adapted and unadapted, it is difficult to claim that adaptation definitely increases the effectiveness of an intervention when used in a culturally diverse group. A fully powered head-to-head randomised controlled trial may be able to better estimate the effect of adaptation in comparing two versions of the same intervention, adapted and not adapted, on the same outcome measures. There may also be factors that moderate or mediate such a relationship, so a regression analysis including variables such as age, gender, proportion of the intervention that was completed and therapy naivety could provide important insight. In terms of pooling data from head-to-head trials already completed (of which there are currently few), an individual patient data meta-analysis could combine more extensive detailed data sets for analysis to better estimate the true effect of adaptation and how moderators and mediators can influence that effect.

In addition to the research methodologies suggested above, it could be helpful to policy makers working in resource-pressured environments to understand which elements of adaptation most increase the effectiveness of an intervention. For example, if a health agency only has limited funds and resources to carry out adaptation, concentrating efforts on one key adaptation area shown to be

most effective would be useful. Combining the above suggested meta-analysis with a questionnaire to researchers as was carried out as part of this thesis could provide further data on the link between adaptation methodology and efficacy of interventions. Whether an element of adaptation was carried out for a given study could be fed into a regression model to understand how much of the variance in the model the given element explains (as well as other mediating factors as mentioned above).

The feasibility test that was carried out as part of this thesis is just the beginning of a series of trials on Step-by-Step in Lebanon and elsewhere on Syrian refugees. A pilot trial has been carried out in Lebanon, and a fully-powered trial is just commencing. In Macau, a pilot trial is planned to take place in the coming months. Having said this, more research on Step-by-Step or other minimally guided app interventions in resource pressured systems is needed, particularly with the high drop-out we have experienced with Step-by-Step. Comparing guided with unguided formats could be particularly helpful in understanding how much added benefit an e-helper model provides and whether e-mental health self-help is also an interesting option for policy makers. An intervention will not be helpful if people do not adhere to it, so further qualitative research into characteristics that increase adherence and into barriers to adherence is necessary. Taking an implementation science perspective on how such a treatment would be integrated in care systems (in an uncontrolled environment), its uptake and adherence and cost benefit analysis would be very important. Positive results would increase the chance that e-mental health becomes globally mainstream and negative ones would shed light on potential barriers and moderators on the potential of e-mental health in diverse contexts.

Chapter 10:

Conclusions

Conclusive remarks

Using one of the largest cross-cultural data sets of the PSYCHLOPS, we demonstrated that using a Western only model of mental distress does not capture important local values. This finding supports the argument that consideration of local priorities and outcomes is important in mental health research and care provision. PGOM could not only be useful in monitoring and evaluation of therapeutic change, as an inlet to therapeutic discussion, but also to inform programme selection and delivery. For example, if one finds that unemployment is a major problem for most of the community prior to running a psychological intervention, the intervention could be tailored to help participants build skills or problem solve in relation to employment or entrepreneurship.

Further research turned to the issue of how adapting an intervention itself can bring added value to its use. The importance of adapting self-help psychological interventions when they are used in diverse cultural settings was demonstrated by the finding that the more an intervention was adapted, the more effective it was. Though the sample size was possibly too small for clear conclusions to be made, nor was the mechanism of this increase in efficacy clear, (e.g., what mediating factors may be at play), we still suggest that cultural adaptation could be very relevant to program managers and treatment providers in diverse settings. Additionally, we call upon researchers to detail and for publishers to facilitate publishing methods and outputs of cultural adaptation efforts. More research needs to be done directly comparing adapted and unadapted interventions, which could facilitate further meta-analysis of individual participant data, controlling for the number of sessions completed and other potentially mediating variables on the efficacy of adapted interventions. With more information on effects and methods of adaptation, decision makers and clinicians can make informed choices around their investment in adaptation procedures.

The process of designing an intervention for use across cultures and contexts has highlighted that flexibility is key when designing an app-delivered psychological intervention for global use. Considering diverse contexts from the outset, we hope that scale-up of the Step-by-Step app will be possible with minimal resources, increasing its potential as a public mental health tool. Further testing which is currently ongoing in a number of sites will help estimate the efficacy of Step-by-Step before it can be made available for free.

In adapting Step-by-Step first to the Lebanese context, and then to overseas Pilipino migrant workers in Macau, we learned a number of valuable lessons. Systematically carrying out and fully reporting methods and results of cultural adaptation research is important in itself, given the lack of detailed accounts of this in the literature. Programme managers and care providers should hopefully be able to appreciate the importance of adaptation and replicate or modify our methods for their own adaptation of interventions. Including potential end-users in a bottom-up approach is crucial in ensuring that their views and preferences can increase the relevance, acceptability and comprehensibility of an intervention. Other stakeholders such as front-line health workers and service managers can also give insight into potential service delivery and acceptability issues.

The feasibility testing of Step-by-Step has provided important research design and intervention revisions ahead of further testing and has proved an indispensable step in the management and planning of further efficacy testing. Though the research had many limitations, the preliminary

results reported hint that Step-by-Step could be an effective intervention among people living in Lebanon.

Further, rigorous testing of Step-by-Step is currently underway with the aim to prove its efficacy in two large trials ahead of the release of the product as a global good. Once such an intervention is integrated into a health system, implementation research will be important to understand the real-world considerations and benefits of employing such innovation into mental health treatment services.

Appendices

Appendix 1: List of abbreviations

CI	Confidence Interval
EASE	Early Adolescent Skills for Emotions
ECR	Essai Contrôlé Randomisé
EH	Eva Heim, Research and Clinical Psychologist at University of Zurich
ERC	Ethical Review Committee
EVM	Ecological Validity Model
GAD-7	Generalised Anxiety and Depression scale, 7 item
HIC	High Income Countries
I^2	Higgins heterogeneity statistic
JAR	Jinane Abi Ramia, Project coordinator, Lebanese Ministry of Public Health
KC	Kenneth Carswell, clinical Psychologist at WHO
LMIC	Low and Middle Income Countries
MhGAP	Mental Health Gap Action Programme
MoPH	Ministry of Public Health, Lebanon
MRC	Medical Research Council
MSc	Masters of Science degree
OMS	Organisation Mondiale de la Santé
PGOM	Patient Generated Outcome Measure
PHCCs	Primary Health Care Centres
PHQ-8	Patient Health Questionnaire, 8 item
PM+	Problem Management Plus
PSYCHLOPS	Psychological Outcome Profile Questionnaire
PTSD	Post Traumatic Stress Disorder
RCT	Randomised Controlled Trial
SES	Socioeconomic Status
SH+	Self-Help Plus
SOPs	Standard Operating Procedures
WHO	World Health Organization
WHO-5	World Health Organization Five wellbeing index
WHODAS	World Health Organization Disability Assessment Schedule
YLD	Years Lived with Disability

Appendix 2: Adaptation monitoring form (Chapter 6)

This form was used to record both data during qualitative research and to monitor the changed being made to the interventions in the adaptation meetings. These cells were reproduced for each adaptation.

Stage of adaptation	Original text including document name and page number	Proposed change	Justification to change original text	Notes	Change agreed
☐ Contextual research ☐ Translation ☐ Pre-testing ☐ Accuracy check ☐ Adaptation during use			☐ Not understandable ☐ Inappropriate ☐ Irrelevant ☐ Other		☐ Yes ☐ No

Appendix 3: Methodological reflections and lessons learned

With the goal of the doctoral programme in Global Health being to bridge the gap between academia and global health, this section of the thesis provides personal reflection on the work completed in order to share lessons learned and practical considerations. Notably, adverse events during the research are summarised.

Chapter 3 methodological reflections: Using PSYCHLOPS in Kenya and Pakistan

The experience of collecting PSYCHLOPS data in Pakistan and Kenya highlighted differences in how the measure was used. It was originally designed as a self-report measure but due to the lower literacy level of the populations studied, it was presented in an interview. The PSYCHLOPS asks for one problem or life limitation in response to its main three questions, and in the peri- and post-intervention versions, asks respondents to reflect back on the problem or limitation they cited pre-intervention. In both settings, enumerators a.) recorded many responses to each question, which were then difficult to code during analysis and, in b.) Kenya, new problems were cited peri-and post-intervention. If PSYCHLOPS is being delivered in an interview, assessors should use an interview schedule with clear instructions. This should include some reassurance of the confidentiality of participant's responses, as social biasing was found to impact the data gathered. This would help to avoid difficulty in assigning codes and difficulty comparing problems pre- to post-intervention.

Social biasing may have affected the results of this study. The paper (chapter three) details accounts by participants and study staff of instances where this likely occurred. One example is that the enumerators in Kenya were from a local NGO which normally help families to pay for school and school supplies, potentially biasing participant's problem responses toward being financial in nature. The process of summarising and translating responses (without them being checked by another bilingual team member as was the case for Kenya) may have diluted or changed responses in some cases, introducing further inaccuracies.

In the Kenya study, there were four serious adverse events at screening stage only (therefore nothing to do with the intervention of the research methods). These persons were not included in the study. Each case was suicidal intent, two cases of which had been planned and three cases of which were accompanied by malnutrition. The clients were given some food supplies and were referred to the nearest hospital for assessment with a psychiatric nurse and care was transferred to the referral hospital where they received antidepressants and some attended follow up sessions (study staff followed up with the hospital staff for four weeks after the incident and where participants did not attend follow up, study staff tried to make contact). In Pakistan, there was one serious adverse event recorded at the beginning of the study. The person was referred to a psychiatrist who assessed her as having severe depression and suicidal thought and started her on an antidepressant as well as making a suggestion that she admits herself to a psychiatric facility. All travel and treatment costs were borne by the research study.

Chapter 4 methodological reflections: Cultural adaptation of self-help interventions, meta-analysis

Part of this study included grading adaptation methodologies, and as is customary in systematic reviews, estimating the risk of bias of the retrieved studies. It was not possible to get the adaptation questionnaire filled in by all study authors, so for two studies, we had to attempt this ourselves on the basis of the little information published in the journal article. Filling out questionnaires or making judgements about the extent of adaptation was not straightforward due to the abstract nature of the adaptation model used (e.g. whether elements of the framework are mutually exclusive) and the construct of culture itself. Through the experience of the past years, while working for my PhD project, I matured some personal reservation in using the frameworks presented in chapter two. Notably, these frameworks' relevance to actually carrying out qualitative research in order to adapt interventions may be minimal and could overcomplicate the process, especially given the abstract nature of the frameworks. They may alienate people who are not specialists in anthropology, for example field-based managers, clinicians and decision makers, by over theorising the process of adaptation, potentially hindering their ability to engage in the process. Also, grading the risk of bias with limited methodological detail in some cases was also difficult.

The study found that with more adaptation to culture and context comes higher efficacy, however this finding should be interpreted with caution for a number of reasons. The search strategy used LMIC countries as a proxy for culturally diverse populations (with the addition of some obviously culturally diverse HIC such as Saudi Arabia and Bahrain). The search strategy would not have captured, for example an American intervention adapted for use in Norwegian culture. As mentioned, there were eight studies with nine datasets included in the analysis (carrying moderate risk of bias) and only six researchers completed questionnaires about adaptation techniques. More trials on self-help in diverse cultures have probably emerged since the systematic search in 2015, so replicating the study may give rise to more data. Also, the studies that were included did not compare an adapted and an unadapted version of the same intervention (which would be the most direct way to ascertain added benefit of adaptation). Finally, the meta-regression did not consider other potential variables such as dose of intervention.

The simple meta-analysis was based on data where five of the nine datasets comprised completers only, possibly inflating the effect size. The Cochrane handbook suggests 10 studies should be the minimum for completing a meta-regression analysis. This study used nine datasets from eight different studies only. With hindsight, it may be more accurate to complete an individual participants meta-analysis and meta-regression while controlling for level of participation (number/proportion) of sessions completed, level of health worker support and the length of intervention as well as some demographic variables.

Chapter 5 methodological reflections: Designing a scalable e-mental health intervention

In designing Step-by-Step, the team had to consider scalability, equity of access and use in diverse and resource pressured settings from the outset. The goal of this project was to create a global product which could be adapted for a number of settings, could potentially incorporate other interventions (in the same delivery platform for example) or other therapeutic content relevant to a given setting (e.g., a session on trauma to be used in conflict-affected settings). See chapter five regarding important design considerations.

Originally envisaged as an e-version of PM+ to treat common mental disorders, the final intervention ended up being predominantly behavioural activation with the elimination of problem-solving approaches. This is because during the peer review process, where 35 international experts reviewed a concept note of the intervention, peers were concerned about it's over ambitiousness, particularly as a brief and possibly unguided intervention. If a person were to use the intervention without guidance, they may struggle with the problem solving content, as it is a skill that can be complex and require coaching to master. This position was upheld, when upon interviewing the clinical supervisor of the two large PM+ trials, she compounded that this was often something that clients and PM+ providers found hard to understand. The intervention only being 5 or 6 sessions in length was also another reason to drop problem solving and some of the cognitive content, with the ethos being to do something well, i.e. concentrate on behavioural activation, rather than deliver many strategies inadequately. Given it was mainly behavioural activation, for which the evidence base is strongest as a treatment for depression, it also became more focused, no longer as a treatment for common mental disorders. Having said this, in testing Step-by-Step, anxiety and wellbeing outcomes will be included, and if efficacious, its treatment scope will be expanded again.

We had to consider the longer-term picture in the facilitation of health services to use and maintain the intervention, (e.g., using open source software and providing programming guides). Additionally, for services serving divergent cultures and contexts, it was important to develop an intervention that could be easily adapted. Writing a story while removing as much culture as possible is challenging, as we learned in creating a "generic" version of Step-by-Step. Much consideration went into the illustrations of Step-by-Step (see chapter 5). We used digital illustrations created using vector graphics, or layers of images, such as the background (first layer) with furniture (second layer) and the character (third layer) and the character's clothes (fourth layer). This means that once an implementer receives the Step-by-Step digital package, revising an image will be more feasible, because just one or two layers of the image (e.g., a character, or the characters facial hair or hijab) could be removed or changed by a graphic designer or digital illustrator, as opposed to having to re-draw the entire image at a cost to the recipient health system. Illustrations were briefed to be simple, with not too much detail that would show for example how old the character was (so that the story is accessible to different age groups), or the characters' socioeconomic status (such not having jewellery or not showing much detail of the type of home the character lives in). Simple illustrations were made in order to be applicable to a wider audience and enable users to project themselves into the story. Cultural adaptation and feasibility testing showed that many considerations were (and will be) necessary to attain the goal of a truly scalable and adaptable product for use in varying contexts.

As with many projects involving a number of contributors and stakeholders, timeline management was key. From the outset, we had accounted for a buffer period in the timeline, but this two month buffer was not sufficient. Mainly due to lengthy contracting processes and the illustrator vastly underestimating the time necessary to complete the illustrations, we were approximately three months behind schedule by the start of the feasibility testing phase. Careful checking of the website (both English and Arabic versions) was also necessary towards the end. Close monitoring and management of expectations was important to ensure the numerous parts of the project moved together.

Chapter 6 methodological reflections: Cultural adaptation of Step-by-Step in Lebanon and Macau

The version used in the qualitative testing in Lebanon was a generic version. In Macau, they used the Lebanese version to present to participants and chose to adapt from that version rather than the generic version. The Lebanese version ended up being much shorter than the original generic version and many of the adaptations made to it were more likely to be representative of any user group. When writing the intervention, we had imagined repetition to be very important in helping users to understand (particularly in an un-guided model of delivery). In Lebanon, potential users did not like the level of repetition at all and so the story was vastly edited down. In Macau, feedback was that there was still some repetition that could have been cut out.

In previous projects at WHO, the team had used a different framework for cultural adaptation often referred to as the Bernal Framework. Proposed in 1995, the Bernal and Sáez-Santiago framework (70,107) was proposed in 1995 and has eight elements of adaptation: language, person (client) attributes, metaphors, content, concepts, goals, methods, and context of the intervention or services. While designing the qualitative research for adapting Step-by-Step, we interviewed the staff who carried out the adaptation of PM+ for Kenya and Pakistan and SH+ for Uganda. They reported difficulties in using the Bernal framework in that its elements are abstract for non-specialists in anthropology or cultural adaptation to understand. They also report (which I second, having used it to quantify extent of adaptations in chapter four), the elements are not mutually exclusive. For example using a self-help delivery method could fall under methods used because of a certain contextual factor (like community insecurity preventing people from visiting health clinics). To reflect earlier work that was done by van Ommeren and colleagues (108), we chose to broadly structure the focus groups and interviews to gather information on three major elements: acceptability (particularly in-offensiveness), relevance and comprehensibility. These are concepts which seemed clearer and potentially easier to use in the field. These three elements formed the basis of the adaptation monitoring forms we used to record and monitor the changes that were being made to each version of the intervention (see appendix 1).

The process of writing, illustrating and adapting the intervention provided many learning points, including:

Adaptation phase	**Suggestion based on experience**
Story translation	If translating into a dialect of a language, translate into classical or written language, then adapt a second version for a local dialect in case the intervention could be used in another lexical region later.
	Keep ample time for checking the translation. Perhaps break this task into smaller steps (e.g. translate half a story to get the tone correct) depending on complexity of the language. Ensure it is checked by people who know local dialect very well.
	In order to increase equity of access to a potentially text-based intervention, run the translation through software to estimate its approximate reading age. Revise text to a reading age of approximately 10 years old so that primary school leavers can engage with it.

	If there are multiple versions of the story aimed at men or women, factor in enough time to make different versions of the translation e.g., gender of audience can result in gendered pronouns and conjugations in some languages.
Story adaptation	On the advice of the Gender and health team at WHO, men and women should do similar activities, while remaining as true to the context as possible.
	Consider specific groups within the target population. For example do some groups follow certain religious rites or customs which would prevent them doing a certain activity or would make them more/less able to relate to the story?
Illustrations	Use an illustrator who is familiar with the target population and where feasible, with the intervention. Alternatively, have advisors who can work with the illustrator to provide illustration briefs.
	Try to make visuals as generic as you can so that the diverse audience can relate to the image and therefore the intervention. Illustrations and visual materials such as videos or photographs should be relevant to all social and economic groups in the target population wherever possible. For example, try not to include very defining features unless absolutely necessary, (e.g. a defining style of dress, physical features, wearing jewellery or items hinting at affluence etc, as this will mean images can be more widely used). If this is not possible, such as when veiled women and non-veiled women are using the intervention, try to have some characters with each characteristic or make separate versions of the interventions for diverse groups.
	Conduct reviews of core characters and core illustration backgrounds with local implementation teams and professionals, then the target population. If possible, revise the characters and test them again before completing the illustrations or a video of the entire intervention, as this may be expensive to change later. After having finalised the core characters and backgrounds, then create the remaining images.
	Check the first session illustrations with the target population first before then illustrating remaining sessions.
	Try to be aware of complexities in the target population and if necessary, minimise them in illustrations or other visual materials. e.g., Some colours or fashion styles be associated with political or religious groups or cause offence.
General	Timetable as much time as your colleagues can allow for an adaptation meeting (meeting with study team held to decide on final adaptations) as there was a lot of data to present and a lot of discussion on changes. The adaptation meeting should either be sufficiently long to cover all sessions (half a day on each intervention session, which is probably not feasible), or have a smaller group make a first round of decisions and elevate up tricky decisions to the wider group.

Make a very clear verification protocol for ensuring the language and images are all correct before publication (e.g., in an App or self-help book).

Chapter 7 methodological reflections: feasibility testing of Step-by-Step

Both cultural adaptation and feasibility testing lead to some important research design considerations that we did not foresee. The e-helper model had to be carefully thought out, because in talking to community women, we realised that being contacted by a stranger, particularly among Syrians, posed a protection concern. The concern was that husbands may become suspicious of who is trying to contact their wives, and some even mentioned that he may become violent. Many women in Lebanon share a phone with their husbands, so privacy was also a concern. Furthermore, (predominantly Syrian) women would not want their husbands to know they were accessing such a programme for fear of being seen as crazy or a bad wife (with some fearing that the husband could have grounds to leave them). We needed to strike a balance between protecting vulnerable women, and enabling equity to access and privacy, so we devised a plan where at sign up, participants could opt for written support through the website (which was passport protected) or through phone calls. It was not necessary to enter a phone number if they did not want telephone support and they could complete the programme without any support if they wished. Additionally, if a participant did select to be supported by phone, during the very first phone call, the participant was asked if they have any requests or preferences in the case of a third party answering the phone. Protocol was to say that they were from a government health programme associated with the local PHCC that was offering a new service to prospective beneficiaries.

During the focus groups for cultural adaptation, participants were asked what time they would like to be contacted, which provided us with a shift structure for e-helpers (8am-midday and 4pm-8pm). Recruiting e-helpers was managed by the local team upon a headquarters-suggested person specification. We had to budget for and estimate how many e-helpers would be needed by considering the length of study recruitment and the shift structure. Through doing role-plays during training, we realised that written support was very time consuming (with the time needed to wait for the other party to reply to a message), so we would need to allow more support time if this method was preferred by the participant. E-helpers were trained over six days, but reported not feeling confident with dealing with complex cases or high risk situations, so the training programme was revised to spend more time doing role plays of such situations. Clinical supervision was carried out by an MoPH clinical psychologist who had a very busy work load, so at times group clinical supervision was not carried out in the way the operating procedures had defined (more ad hoc and individually over the phone rather than all together at weekly set time), though they always had a weekly peer support session with the local project coordinator. In future research, the clinical supervisor would be external to the MoPH and hired specifically for that task. E-helpers also reported being asked personal questions or feeling that the participant became overly attached to them, so perhaps clarifying the role and relationship with the e-helper in an FAQ section could be helpful.

Recruitment was more difficult than we had envisioned, and we learned through a question on sign – up (where did you hear about Step-by-Step) that recruiting through PHCCs was not very fruitful. Website analytics showed us that Facebook advertising through selected Facebook groups was most

effective (we were limited by the MoPH to student groups and the MoPH Facebook group). Whatsapp groups for students were also used. In further research, social media will be the predominant means of recruitment, accessing larger and more diverse networks. Of the small participant pool, very few were Syrian. Ahead of the next phase of testing, the MoPH has already managed to partner with UNHCR and the International Medical Corps for assistance with recruitment through their services for refugees.

Responses during the qualitative process evaluation interviews provided some important information as to the acceptability of the intervention. Overall, people were positive about e-mental as an innovative way to provide care but suggested that acceptance would take time (as with any innovation). Some participants were resistant to non-specialists providing the guidance, showing a preference for trained therapist help. Managing expectations around this aspect of the intervention may be necessary in future research phases or scale up, but presenting (in a clear and understandable way) evidence in the introduction or FAQs section of the intervention that non-specialist delivered interventions work could be a starting point. Normalisation of distress and mental health problems was a key finding, with many participants being relieved to find that their experience is typical and didn't mean they were crazy. Participants suggested further tailoring of the intervention for younger, single persons, so a further version of the story has been written, so that at the beginning of Step-by-Step, users can choose between an older character (in their 30's or 40's with children) or a younger character (in their 20's with no children). Content such as activities and problems (i.e., exam stress, or activities involving the children) will also be tailored.

Adherence was also a major problem in this study, with 59% of people who started the intervention dropping out. By the time we carried out the feasibility testing, we had already decided to programme the intervention into an app. Due to limited budget for the formative phase, we could not start with an app, so chose to run Step-by-Step using a website in order to gage the acceptability of e-mental health and figure out such design issues as detailed above. The process evaluation gave some insights into actions to take in subsequent testing to try to ameliorate adherence, so ensuring that an app version has minimal technical problems and using push notifications to help motivate users. An app will also enable users to use the app offline (with free wifi offered at PHCCs for the initial download of the app), costing them less in data usage and thereby increasing equity of access.

There were two adverse events during the data collection phase of this study. Despite participants being screened out of the study if they answered affirmatively to a screening question on suicidality, two participants disclosed to an e-helper that they had suicidal ideation. Neither of the participants had said that they had a plan upon enquiry by the e-helper. As per protocol, the participants were referred to the national suicide helpline and informed of where their nearest suicide-trained emergency room or primary care clinic was. The e-helper got guidance from his clinical supervisor and kept more regular contact with the participant until the clinical supervisor deemed them to no longer be at risk (daily, then twice a week). The e-helper disclosed having been stressed by his experience of handling the calls where suicide was discussed. In future iterations of this research, e-helpers will receive more training on handling difficult calls such as these.

Appendix 4: About the author

Melissa is a dedicated public health practitioner and researcher. Her career so far has included clinical, technical and research work mainly on low-resource-intensity psychological interventions. Melissa grew up in Bristol, in the south-west of the UK and has been living in the Geneva area since 2012.

Melissa completed a bachelor's degree in Psychology at the University of the West of England (UWE) in 2008, then in 2009-10 she completed a one year, part-time post-graduate certificate in counselling skills, also at UWE. While studying, Melissa did voluntary work for the UK National Autistic Society and the National Association for the Children of Alcoholics. To finance her studies and gain some relevant experience, she worked part time on a range of inpatient psychiatric wards as a health care assistant and as a telephonist at an insurance company. In early 2009 she started full-time as a mental health worker for an inpatient drug and alcohol detox facility, assisting with nursing and co-designing and running the psychotherapeutic programme, which was key to the detoxification process.

In 2010, Melissa moved from Bristol to London to pursue her Masters of Science (MSc) degree in Mental Health and Psychological Therapies. This course at Queen Mary University consisted of three main modules: Advanced cross-cultural mental health assessment; Psychological intervention theory with transcultural focus; and Research methods, including evidence synthesis. As part of the course, Melissa also completed a 6 month, part-time clinical placement as an assistant clinical psychologist at the Camden and Islington drug service. Under the supervision of the head clinical psychologist, two days a week she would carry out triage assessments, manage a small caseload of clients and run a group CBT insomnia and sleep intervention.

In early 2012, Melissa arrived in Geneva and attended French language school for 6 months. Having not gained equivalence for her UK MSc by the Swiss Federation of Psychologists, she prepared herself for studying a Swiss MSc followed by a Master of Advanced Studies in order to become a clinical Psychologist. Between finishing French School and starting University again, Melissa did a three month internship in the department of Mental Health and Substance Abuse at WHO, working on the conceptualisation of PM+ and on a mental health care situation analysis guidance package. Having thoroughly enjoyed the work at WHO, after two months of the MSc programme, she decided to follow a career in public mental health, offering herself as a consultant to WHO. The first contract she got was at 50%, so she complimented this with a three month 50% internship in the policy development and evaluation service at UNHCR.

For her first two years as a consultant at WHO, (2013-2015) Melissa worked on three principle projects: The International Classification of Diseases revision, neurology chapter; The neurology atlas (mapping of global resources for neurology); and the WHO mental health and substance use guidelines revision project. In 2015 and with the start of the PhD programme, she moved sub-teams to work again on scalable psychological interventions, where her main role was as project manager for Step-by-Step but contributing regularly to other research and design projects for psychological interventions. A short CV follows:

EDUCATION

PhD in Global Health 2015 to 2020. *Institute of Global Health, University of Geneva, Switzerland*
Master of Science with distinction in Mental Health and Psychological Therapies 2011. *Barts and the London School of Medicine and Dentistry, Queen Mary University of London, UK*
Certificate in Counselling Skills *(British Association of Counsellors and Psychotherapists accredited)* 2010. *University of the West of England, Bristol, UK*
Bachelor of Science with Honours in Psychology *(Upper 2.1,* British Psychological Society*)* 2008. *University of the West of England, Bristol, UK*

GLOBAL HEALTH EXPERIENCE

Consultant – Department of Digital Health and Innovations: *World Health Organisation (WHO), Geneva, Switzerland.* 2019-present
-Production management and marketing to ministries of health guidance packages for national-level mHealth programming.

Consultant – Fondation d'Harcourt, Geneva, Switzerland. 2019
- Monitoring and evaluation toolkit for their portfolio of grantees.

Consultant – *Department of Reproductive Health Research: World Health Organisation (WHO), Geneva, Switzerland.* 2018
- Psychosocial intervention to improve sexual and reproductive health and mental health outcomes for Syrian refugees in Turkey.

Consultant –*Department of Mental Health and Substance Abuse: WHO, Geneva, Switzerland*. 2013 – 2018
- Scalable psychological interventions or use in low and middle income countries.
- Mental health Gap Action Programme (mhGAP) guidelines.
- International Classification of Diseases (ICD) 11th edition, Diseases of Nervous System chapter.
- Atlas: Country Resources for Neurological Disorders.
- Multinational WHO mhGAP Epilepsy Initiative.

Assistant Editor (journal) – *War Trauma Foundation, Amsterdam, the Netherlands.* 2018
-Assistant editor of the journal "Intervention: Journal of Mental Health and Psychosocial Support in Conflict Affected Areas"

Consultant – *National Mental Health Programme: Lebanese Ministry of Public Health*. 2018.
- Fundraising toolkit

***Intern – UN High Commissioner for Refugees (UNHCR), Geneva, Switzerland*.** 2013
- Evaluation of urban refugee policy with regards to acculturation theory and mental health of refugees.

Intern - ***Mental health, Evidence and Research team, Department of Mental Health and Substance Abuse: WHO, Geneva, Switzerland.*** 2012
- Conceptualisation of a manualised psychological intervention for high prevalence mental disorders: Problem Management Plus; and mhGAP situation analysis and M&E toolkits.

TEACHING EXPERIENCE

University of Zurich, Division of Psychopathology and Clinical Intervention AND University of Geneva, Institute of Global Health
- Annual two-part lecture and interactive workshops on global mental health guidelines

development with simulated guidelines development group for Clinical Psychology/Global Health Master's students.

CLINICAL EXPERIENCE

Assistant Clinical Psychologist - ***Camden Drug Service: Camden and Islington NHS Foundation Trust, London, UK.*** 2011
Mental Health Worker - ***Bristol Specialist Drug and Alcohol Service: Avon and Wiltshire Mental Health Partnership NHS Trust (AWP), Bristol, UK.*** 2009-2010
Health Care Assistant - ***Psychiatric Intensive Care Unit: AWP, Bristol, UK.*** **2008**
Care Support Worker on a range of mental health inpatient wards - *NHS Professionals, UK. 2008-2011*

VOLUNTARY WORK

War Child Holland, Amsterdam, the Netherlands: Member of Ethics Review Board, 2018-present
Geneva Health Forum Conference, Geneva, Switzerland: Conference workshop organiser, 2015-16
National Association for the Children of Alcoholics, Bristol, UK: Helpline Volunteer and Public Speaker, 2010-2012
The National Autistic Society, UK: Befriender to a child with autism, 2010-2013
University of the West of England: Research assistant in autism research project, 2007

LANGUAGES

English-Native speaker; **French**-Diplome d'Etudes en Langue Française level B2; **Arabic**-Beginner.

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