EFFECT OF CULTURAL ADAPTATION OF A SMARTPHONE-BASED SELF-HELP PROGRAMME ON ITS ACCEPTABILITY AND EFFICACY: STUDY PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

EFFECT OF CULTURAL ADAPTATION: STUDY PROTOCOL

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Abstract

Background: In order to narrow the world-wide treatment gap, innovative interventions are needed that can be used among culturally diverse groups, e.g., immigrant populations in high-income countries. Research on cultural adaptation of psychological interventions indicates that a higher level of adaptation is associated with a higher effect size of the intervention. However, direct comparisons of different levels of adaptations are scarce and have not been done with self-help interventions.

Aims: This study will use a Smartphone-based self-help programme called Step-by-Step (Albanian: Hap-pas-Hapi) for the treatment of psychological distress among Albanian-speaking immigrants in Switzerland and Germany. Two levels of cultural adaptation (i.e., surface vs. deep structure adaptation) will be compared. We hypothesise that the deep structure adaptation will enhance the acceptance and effect size of the intervention. The deep structure adaptation was done based on an ethnopsychological study to examine the target population's cultural concepts of distress.

Methods: We will conduct a two-arm, single-blind randomised controlled trial. Participants will be randomly assigned to the surface vs. deep structure adaptation version of Hap-pas-Hapi (1:1 allocation using permuted block randomization). Inclusion criteria are good command of the Albanian language, age above 18, and elevated psychological distress (Kessler Psychological Distress Scale score above 15). Primary outcome measures are the total score of the Hopkins Symptom Checklist and the number of participants who completed at least three (out of five) sessions. Secondary outcomes are global functioning, well-being, symptoms of post-traumatic stress, and self-defined problems. In addition, we will test a mediation model, hypothesizing that the deep structure adaptation will address fatalistic beliefs and enhance alliance with the self-help programme, which in turn increases the acceptance and effect size of the intervention. And finally, we will measure acculturation and

hypothesise, that with higher levels of acculturation, the effect of the deep structure adaptation will diminish.

Discussion: This is the first study to directly compare two different levels of cultural adaptation of an online self-help programme for the treatment of psychological distress among immigrants in high-income countries. We aim to deliver theory-driven and methodologically rigorous empirical evidence regarding the effect of cultural adaptation on the acceptance and effect size of this self-help programme.

Trial registration: clinicaltrials.gov NCT04230135

Key words: Cultural adaptation, psychological interventions, mobile mental health, self-help, immigrants, online interventions, cultural concepts of distress, fatalism, working alliance, acculturation

Highlights

- In cultural adaptation research, empirical evidence based on experiments is scarce.

- Internet-based interventions can be used for this purpose, as content can be changed easily.

- This study will compare two levels of cultural adaptation: surface vs. deep structure adaptation

- We hypothesise that the deep structure adaptation will enhance treatment adherence and efficacy.

1-sentence teaser

Experimental designs are needed to advance our knowledge on cultural adaptation. Such research may contribute to better understand the mechanisms of action in psychological interventions.

Background

Common mental disorders (CMDs) such as depression, anxiety, and post-traumatic stress disorder (PTSD) contribute to a significant burden of disease worldwide (Whiteford et al., 2013), particularly among populations affected by armed conflicts and migrant populations (Charlson et al., 2016; Turrini et al., 2017). Negative effects of violent conflicts and migration on mental health often persist over years or decades (de Jong et al., 2003), e.g., in survivors of the Balkan wars (Bogic et al., 2015; Priebe et al., 2010). Effective, affordable and safe psychological interventions for the treatment of CMDs exist (Munder et al., 2018; Smith & Glass, 1977; Wampold & Imel, 2015) and have increasingly and successfully been tested among culturally diverse groups (Cuijpers et al., 2018; Singla et al., 2017; van Ginneken et al., 2013). However, due to barriers such as mental health-related stigma and lack of resources, a high number of people affected by CMDs still do not receive adequate treatment (Demyttenaere et al., 2004).

According to the World Mental Health Survey, the treatment gap (i.e., percentage of people in need of treatment who have not received adequate treatment) for CMDs is around 60% in high-income countries (HIC), 65% in upper-middle-income countries, and over 80% in lower-middle-income countries (Alonso et al., 2018; Thornicroft et al., 2017). In HIC, access to mental health care is particularly limited for culturally diverse groups (i.e., asylum seekers, refugees, and other migrants), due to barriers such as poor command of the host country language, cultural beliefs about mental health, lack of trust towards mental health services, and mental health-related stigma (Priebe et al., 2016).

Evidence from the field of cultural clinical psychology shows that the validity of diagnostic categories developed in Western, Educated, Industrialised, Democratic, and Rich (WEIRD, Henrich et al., 2010) countries may be limited when applying them in other cultural groups, a fact that is also known as the "category fallacy" (Kleinman, 1977). In other words, symptom patterns found among different cultural groups do not necessarily correspond to the

symptom patterns that were agreed to be diagnosed as "major depression" or "panic disorder" in our current diagnostic manuals. It is for this reason that the Lancet Commission on Global Mental Health and Sustainable Development (Patel et al., 2018) strongly suggests moving towards "dimensional approaches of symptom spectra rather than discrete categories of mental disorder" (p. 11). Especially at less severe stages, symptom patterns of CMDs may largely overlap and can therefore be better described more generally in terms of "psychological distress" (Ryder & Chentsova-Dutton, 2015).

Internet-based interventions to address the mental health treatment gap

Internet-based interventions are currently propagated as one potential measure to address the worldwide mental health treatment gap (Schröder et al., 2016). A large number of randomised controlled trials (RCTs) tested the efficacy of internet-based interventions and delivered promising effect sizes. An umbrella review of recent meta-analyses showed effect sizes of d/g = 0.44 – 0.9 for depression and d/g = 0.7 – 1.31 for different anxiety disorders (Andersson et al., 2019). Most of these trials were conducted in HIC, although there is a growing number of studies testing Internet-based interventions among culturally diverse groups (Naslund et al., 2017). Ethnic minorities are generally under-represented in clinical trials in HIC (Hussain-Gambles et al., 2004; Wendler et al., 2005), and there is a lack of evidence on the extent to which results from one cultural group can be transferred to another one.

One RCT in the Netherlands examined the efficacy of a culturally adapted online-intervention for the treatment of depression among Turkish immigrants (Ünlü Ince et al., 2013). No significant difference was found in symptom improvement in the experimental group compared to the control group, although the same intervention had shown a medium effect size in a Dutch sample (van Straten et al., 2008). Results might be explained by the small sample size (and hence low power), but the drop-out rate among Turkish participants was 42% at post-test and 62% at three-months follow-up, compared to 17% at post- and follow-up in the Dutch sample.

World Health Organization (WHO), in collaboration with the Ministry of Public Health in Lebanon, the Freie Universität (FU) Berlin, and the University of Zurich, have developed an online intervention called Step-by-Step for the treatment of depression among culturally diverse groups (Carswell et al., 2018). Effectiveness and cost-effectiveness of Step-by-Step will be tested in three parallel RCTs among Syrian refugees in Germany, Sweden, and Egypt ($N = 500$ per site) within the EU-funded STRENGTHS project (Sijbrandij et al., 2017), and in two parallel RCTs among Syrian refugees and other people residing in Lebanon ($N = 500$ per group), under the lead of WHO and the Lebanese Ministry of Public Health. Step-by-Step was written in English and developed in a "generic" approach, designing illustrations and narratives in a way that they can potentially speak to people from different contexts (Carswell et al., 2018). Thereafter, it was culturally adapted for different cultural groups living in Lebanon (Abi Ramia et al., 2018).

Cultural adaptation

There is an ongoing debate on the extent to which cultural adaptation of psychological interventions contributes to their acceptability, efficacy, and effectiveness. Empirical evidence from ethnopsychological studies has revealed cultural variety in so-called idioms of distress, i.e., the way how symptoms of CMDs are expressed (Haroz et al., 2017; Kohrt et al., 2014), and how different cultural groups explain the emergence of such symptoms, which is also known as explanatory models (Bhui & Bhugra, 2002; Bhui et al., 2006). Explanatory models reveal people's implicit assumptions about mind-body relationships and religious or spiritual beliefs (e.g., Kohrt & Hruschka, 2010). In DSM-5, culturally diverse idioms of distress and explanatory models are subsumed under the term cultural concepts of distress (CCD) (American Psychiatric Association, 2013; Kohrt et al., 2014). In literature, different ways of adapting psychological interventions to such CCD are discussed (Heim & Kohrt, 2019).

Bernal et al. (2009) define cultural adaptation as "the systematic modification of an evidence-based treatment (EBT) 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" (p. 362). Bernal and colleagues (Bernal et al., 1995; Bernal & Sáez-Santiago, 2006) proposed a framework of cultural adaptation which includes eight elements, i.e., language, metaphors, therapeutic relationship, treatment goals, content, methods, concept, and context of the intervention. Most studies on cultural adaptation have focused on face-to-face treatments, but there is an increasing number of studies that systematically describe the cultural adaptation of internet-based interventions. As an example, Salamanca-Sanabria et al. (2019) adapted an internet-based intervention for the treatment of depression in Colombia. They used a mixed method approach, which integrated several frameworks for cultural adaptation. Furthermore, they designed the Cultural Relevance Questionnaire (CRQ) to systematically assess culturally relevant information for adapting the intervention.

Current evidence on cultural adaptation of psychological interventions leaves many questions open. In a meta-analysis, Griner and Smith (2006) found a moderate effect size for the comparison of culturally adapted interventions with different control conditions ($d = 0.45$). Two meta-analyses, one of which focused on minimally guided interventions only, revealed that the efficacy of interventions increases with the number of implemented adaptation elements of the Bernal framework (Harper Shehadeh et al., 2016; Smith et al., 2011). Benish et al. (2011) showed that cultural adaptation of the "illness myth," i.e., the explanatory model provided to patients for their symptoms, was the sole moderator of larger effect sizes of culturally adapted psychotherapy when compared to other active treatments ($d = 0.21$). Moreover, the most recent meta-analysis found a medium effect size (Hedge's g = .52) for the direct comparison between culturally adapted and non-adapted versions of the same intervention (Hall et al., 2016). This finding was based on only nine (13% of the totally included) studies, all of which were face-to-face treatments. More research is needed to study such direct comparisons, especially in the field of self-help interventions, where such direct comparisons have not been done so far (Harper Shehadeh et al., 2016).

For direct comparisons, it is essential to define the levels of cultural adaptations to be compared. Resnicow et al. (1999) differentiate between *surface* and *deep structure* adaptations to health interventions. Surface adaptations refer to matching materials (e.g., illustrations, language), as well as channels and settings for treatment delivery to observable characteristics of the target population. By contrast, deep structure adaptations take into account how cultural, social, environmental, or historical factors influence health behaviours. Such adaptations are based on assumptions of how members of a particular cultural group perceive the cause, course, and treatment of a particular illness. In a new conceptual framework, Heim and Kohrt (2019) suggest adapting psychological interventions to CCD, i.e., to the idioms of distress and explanatory models of the target population. Adaptations to CCD can be considered as deep structure adaptations as defined by Resnicow et al. (1999).

When adapting interventions to CCD, addressing fatalism might be one key aspect. An ethnopsychological study among Albanian-speaking immigrants in Switzerland (Shala, Morina, Salis Gross, et al., 2020) showed that participants understood their suffering as part of normal life, given by God or fate (*fati*), and something that cannot be cured but has to be borne with endurance (*durim*). The concept of fate is also described in Islamic understandings of suffering: "The notion of qadar (قَدَر, 'fate') is central to this context. This acceptance of fate should not be equated with fatalism, but can be better understood within a framework of self-abandonment, which is reflected in the value of patience in the face of helplessness and adversity, such as illness and loss. Life may be viewed as a transient phase of existence, a testing place for the eternal life that comes after death" (Hassan et al., 2015, p. 27).

A similar concept of suffering has also been described among Turkish immigrants in Germany (Franz et al., 2007; Reich et al., 2015). When compared to German patients, Turkish immigrants show more fatalistic-external control attributions for mental distress, which results in lower motivation for psychotherapy. Based on these findings, Reich et al. (2019) developed a web-based intervention to enhance motivation for psychotherapy among Turkish

immigrants in Germany. In a pilot study, they found that this intervention enhanced treatment motivation and reduced fatalistic beliefs. Fatalism might therefore be a relevant aspect in cultural adaptation of psychological interventions for migrants.

It seems plausible that decreasing fatalism contributes to enhanced treatment motivation and adherence. In addition, addressing fatalism may have an effect on symptom improvement that goes beyond increased adherence. Providing a convincing treatment rationale is most likely one of the most powerful unspecific factors in psychotherapy (Gaab et al., 2019; Wampold, 2007; Wampold & Imel, 2015). Fostering the belief that distress can be reduced and well-being can be increased through the use of psychological techniques most likely has an effect on symptoms on its own, aside from the specific effect produced by the techniques themselves. This is not to be confounded with the well-known "placebo-effect" – i.e., an observed symptom improvement based on the belief that a treatment is helpful, even if no treatment is provided at all (Enck et al., 2013). Rather, providing a treatment rationale induces hope and strengthens self-efficacy (i.e., the belief in one's capabilities to do something to feel better). Such a treatment rationale most likely has healing effect itself and can therefore be considered as an "active ingredient" of psychological treatment (Gaab et al., 2019).

Acculturation

When examining the impact of cultural adaptation on the acceptability and efficacy of a self-help intervention among immigrants in HIC, different levels of acculturation have to be taken into account. Acculturation refers to the process of change and adaptation when individuals come into contact with other cultures (Gibson, 2001). Levels of acculturation vary greatly among immigrants. According to current literature, acculturation is a multi-dimensional concept that includes different aspects of change, such as cultural practices, values, and identifications, and very much depends on the moment in life when people migrate (Schwartz et al., 2010). A multi-dimensional concept of acculturation takes into account that individuals

may adapt to some aspects of a culture (e.g., general rules and behaviour) while discarding others (e.g., values).

Moreover, individuals may adapt to a new culture without necessarily losing their culture of origin. Berry (1980) identified three categories of acculturation: *assimilation* (i.e., adoption of the receiving culture while discarding the heritage culture), *separation* (i.e., reject of the receiving culture while retaining the culture of heritage), and *integration* (adoption of receiving culture while retaining the culture of heritage). Integration, also known as biculturalism, is associated with most favourable psychosocial outcomes, particularly among young immigrants (Schwartz et al., 2010). No evidence exists on the question of whether such levels of acculturation are related to cultural adaptation needed in face-to-face and self-help interventions for immigrants in HIC.

In the present study, we aim to compare surface vs. deep structure adaptation of the online intervention Step-by-Step (Albanian: Hap-pas-Hapi) for Albanian-speaking immigrants in Switzerland and Germany. We conducted an ethnopsychological study to examine the target group's CCD (Shala, Morina, Salis Gross, et al., 2020). This study revealed specific idioms of distress, which will be used for the deep structure adaptation. The study also showed that the target population held fatalistic beliefs. A modified version of the intervention developed by Reich et al. (2019) will be used in the deep structure adaptation of Step-by-Step in the present study.

Methods

Aims and design

The culturally-adapted, Smartphone-based self-help intervention called Hap-pas-Hapi for the treatment of depression will be tested in a two-arm, single-blind randomised controlled trial (RCT) among Albanian immigrants in Switzerland and Germany. Hap-pas-Hapi is the Albanian translation of Step-by-Step that was developed by WHO in collaboration with other partners (Carswell et al., 2018). Hap-pas-Hapi starts with an introduction and then offers five

sessions (see below). In this study, one group will have access to the generic, Albanian translation of Hap-pas-Hapi that only includes surface adaptations (Resnicow et al., 1999), and the other group will receive a version of Hap-pas-Hapi that was adapted to the target populations' CCD (i.e., deep structure adaptation). For reasons of simplicity, the two versions will be called "generic" and "adapted" throughout this paper. The deep structure adaptation was done based on an ethnopsychological study conducted in the target population (Shala, Morina, Salis Gross, et al., 2020) and is described more in detail elsewhere (Shala, Morina, Burchert, et al., 2020). Based on current literature, we hypothesise higher efficacy (first primary outcome) and treatment adherence (second primary outcome) in the adapted when compared to the generic version.

More specifically, we hypothesise that the deep structure adaptation will decrease participants' fatalistic health beliefs (Reich et al., 2019) and enhance their working alliance with the programme (Gomez Penedo et al., 2019). We hypothesise that fatalistic beliefs will mediate the relationship between cultural adaptation and efficacy (first primary outcome), and working alliance will mediate the relationship between cultural adaptation and adherence (second primary outcome). A mediation effect can only be shown if the change in the mediator occurs before the change in symptoms (Lemmens et al., 2016). Therefore, working alliance will be measured at the end of the introduction and session 1. Fatalistic health beliefs and severity of symptoms will be measured before starting session 3, and at the end of the programme (for assessments and time points, see Table 1).

Finally, we will test whether the required cultural adaptation of an intervention interacts with the level of acculturation among the target population. More precisely, we assume that the less Albanian-speaking immigrants adopt the receiving (i.e., Swiss and German) culture and the more they retain their culture of origin, the higher the effect of cultural adaptation on treatment adherence and efficacy.

Participants

Inclusion criteria are: a) Albanian-speaking, b) age 18 or above, c) a score of 15 or higher on the Kessler Psychological Distress Scale (K10, Kessler et al., 2002), Albanian version (Hyseni Duraku et al., 2018), and d) access to Internet (Smartphone or web-browser on tablet or computer). Exclusion criteria are: a) living outside Switzerland and Germany, b) serious suicidal thoughts or plans (self-assessed with a corresponding question). We assume that people with severe mental disorders (e.g., acute psychosis) would not be able to sign-up and go through the onboarding procedure, so there will be a self-selection of people with mild to moderate common disorders. However, we do not explicitly screen for and exclude people due to severe mental disorders.

Procedure

Participants will be recruited through two streams: social media (e.g., Facebook, Instagram, and Twitter) and health services (e.g., general practitioners, psychiatric services). Social media recruitment has proven to be an effective recruitment strategy in e-mental health research (Kayrouz et al., 2016; Whitaker et al., 2017), and was used in a pilot study with the Arabic and English version of Hap-pas-Hapi, called Step-by-Step, in Lebanon (Harper Shehadeh et al., 2020). For recruitment, an account in Albanian language with the title "Hap-pas-Hapi" will be created on Facebook, Instagram, and Twitter. These pages regularly refer to the study (at least three times a week), with specially created graphics and photos and the recruitment text on the flyer as the comment of the graphic or photo. The social media messages will be shared by the accounts of the research team, as well as on pages of Albanian associations, and health institutions that have a connection to Albanian clients and patients. In addition, we will post a short movie in Albanian language in which members of the research team invite people to participate.

    Interested people will be free to access the study information and informed consent procedures online, all of which are presented in Albanian language. Applicants will be

reminded that they are free to decline to participate or withdraw at any time. After giving consent, participants will be asked to create an account, will first complete the screening questionnaires, and (if screened positive) complete the additional baseline questionnaires. Applicants who are excluded based on one of the exclusion criteria receive an on-screen message thanking them for their interest in the study, and explaining that they cannot participate in this study at this point. People who answer "yes" on the question about imminent risk of suicide receive a message saying that it is important that they seek help, and providing a list of crisis intervention centres in Switzerland and Germany, along with numbers for telephone counselling in both countries.

Included participants can use the intervention and will be invited for post-assessments six week after baseline assessments. Three months later, they will be invited for follow-up assessments. All measures (pre-, post- and follow-up) will be completed online. As soon as the assessment is due, participants see them as a new "session" on their home screen within the Hap-pas-Hapi programme. If they use the mobile version and agreed to receive automated notifications, they will receive a pop-up message saying that the assessments are due. E-helpers will send a maximum of three reminders for post- and again for follow-up assessments.

Randomisation

After sign-up, informed consent and baseline assessment, participants will be randomly allocated to one of the two treatment conditions. In the study information, participants learn that they will be randomised into one of two conditions, but we do not provide any further information on the differences between the two versions of Hap-pas-Hapi. Randomisation and group allocation (1:1) are done automatically by the system. A permuted block randomisation algorithm (random block lengths of 4, 6, or 8) will be used. All assessments will be done online, and the study team does not have access to data or randomisation during the trial.

Participants will be informed that they will be allocated to one of two versions of Hap-pas-Hapi, but they will be blind to the condition they are allocated to.

Sample size

Based on previous evidence for the effect of cultural adaptation on intervention efficacy (Benish et al., 2011; Griner & Smith, 2006; Hall et al., 2016), we expect a small to medium effect size ($d = 0.45$). As we have two primary outcomes (i.e., symptom reduction (continuous) and treatment adherence (dichotomous), sample size was calculated for both of them individually, with a Bonferroni correction of the alpha level (Vickerstaff et al., 2015; Vickerstaff et al., 2019). Subsequently, the larger resulting sample size, which was the one for symptom reduction, was chosen. In addition, we account for expected drop-out rates around 50%, as shown in an uncontrolled pilot study with Step-by-Step (Harper Shehadeh et al., 2020). In the meantime, several adjustments were made to the intervention, due to which we expect a slightly lower drop-out rate (40%). Assuming a power of 0.80, an alpha of 0.025 (including the Bonferroni correction for two primary outcomes), and an estimated effect of $d = 0.45$, the trial needs to have 96 participants per arm (total sample size: N = 192). Accounting for 40% drop-out, we need 320 included participants (after screening) to make sure the trial is sufficiently powered. A higher number of participants will also be beneficial for increasing the validity of multiple imputation. A flow chart is presented in Figure 1.
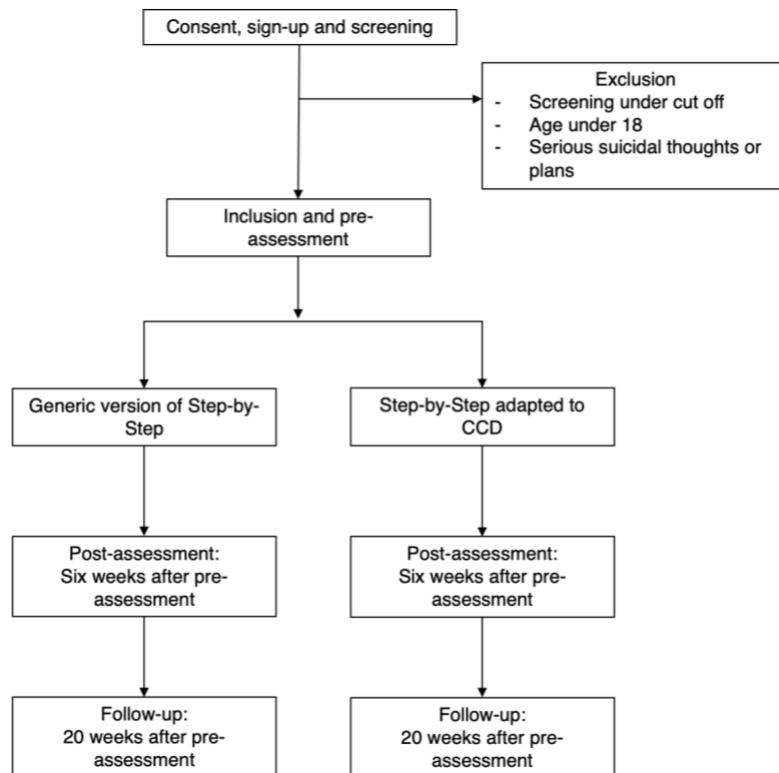
Figure 1. Flow chart

Intervention

Step-by-Step is an online intervention that can be accessed through a mobile app (iOS or Android) or a web browser. The original intervention Step-by-Step uses a narrative approach, in which an illustrated character tells his recovery story. An illustrated doctor narrator provides psychoeducation and interactive exercises. Step-by-Step includes five sessions, and the therapeutic components are behavioural activation, stress management, positive self-talk, mood tracking, strengthening social support, and relapse prevention (Carswell et al., 2018). In the Step-by-Step trials in Lebanon, so-called "e-helpers" – trained lay helpers supervised by a clinical psychologist – provide 15 minutes of weekly support through chat or phone. E-helpers proactively contact users to offer them support and ask how they are doing with the programme. At the same time, FU Berlin has developed a "contact on-demand" model, a principally unguided version of Step-by-Step where users have the option to contact e-helpers

for specific questions. In this model, e-helpers respond to users' questions but do not proactively reach out to participants. The three RCTs in the STRENGTHS project (Sijbrandij et al., 2017) will use this contact-on-demand model. In view of feasibility and costs, the present study will use the same contact-on-demand model as used in the STRENGTHS trials.

Step-by-Step was translated into Albanian language (named Hap-pas-Hapi) and adapted in two different manners. The first, surface adaptation (Resnicow et al., 1999) followed the same procedures as the cultural adaptation that was done in Lebanon (Abi Ramia et al., 2018). The deep structure adaptation was done based on an ethnopsychological study conducted in the target population (Shala, Morina, Salis Gross, et al., 2020) and includes three components: i) idioms of distress of the target population, ii) a new exercise, in which the treatment rationale is adapted to the target populations' explanatory models, and iii) a goal-setting task, which aims to address participants' socio-centric concept of the self (Kirmayer, 2007). The goal-setting task focuses on the potential benefits of using Hap-pas-Hapi for the family or community at large. The deep structure adaptation is described more in detail elsewhere (Shala, Morina, Burchert, et al., 2020).

Screening measure

The K10 (Kessler et al., 2002) will be used as screening measure. It includes ten items on psychological distress that are scored on a Likert scale from 1 to 5. The K10 was found to be an accurate screener for common mental disorders in patients in India (Patel et al., 2008), in Arabic-speaking Moroccans in the Netherlands (Fassaert et al., 2009) and other studies in high-income countries (Sulaiman-Hill & Thompson, 2010). The sum of the ten items gives a total score ranging from 10 to 50. In line with the STRENGTHS study, we will use a score of >15 as an indication of moderate to high levels of psychological distress (de Graaff et al., 2020).

Primary outcomes

The first primary outcome is the Hopkins Symptom Checklist (HSCL-25), which consists of 25 items related to psychological distress (Derogatis et al., 1974). It includes subscales for depression (13 items) and anxiety (10 items). In addition, two items assess somatic symptoms. The items are rated on a 4-point Likert scale. The HSCL-25 has been translated into Albanian and back-translated (Lopes Cardozo et al., 2005), and has been used in several studies with Albanian-speaking participants (Lopes Cardozo et al., 2005; Schick et al., 2013).

The second primary outcome is treatment adherence, defined as completing at least three (out of five) sessions. The reason for this definition of treatment adherence is the fact that the main adaptations were done in the first two sessions. Thus, after session 3, we would not expect group differences with regard to adherence, because the intervention versions are identical. Use of the intervention (i.e., start and completion of sessions, exercises) will be automatically registered by the online platform. In the Step-by-Step pilot trials, a large number of participants (58%) did not move from the introduction to session 1, and another 30% dropped out between session 1 and session 3. Data also showed that if users complete session 3, they are likely to complete the intervention and improve in symptoms (Harper Shehadeh et al., 2020). In this study, the deep structure adaptations for the intervention condition are made in the introduction and session 1. Therefore, we assume that the main effect will be on adherence in these first sessions. Additionally, the number of sessions completed will be looked at as a sensitivity analysis.

Secondary outcomes

The WHO Disability Assessment Schedule (WHODAS) 2.0 is a generic assessment instrument assessing health and disability (Rehm et al., 1999). It is used across all diseases, including mental, neurological, and substance use disorders and in many global regions. It is simple to administer, applicable across cultures, and can be used in all adult populations. WHODAS covers six domains (cognition, mobility, self-care, getting along, life activities,

participation). It assesses difficulties people have across these domains during the last 30 days. Difficulties are scored as none, mild, moderate, severe, or extreme. The WHODAS 2.0 has been translated and back-translated for this study.

The WHO Well-being Index (WHO-5) is a 5-item questionnaire measuring current psychological wellbeing and quality of life, rather than psychopathology (Bech et al., 2003). Scores range from 0-25. The scale has demonstrated sensitivity to change in wellbeing and is available in multiple languages.

PTSD symptoms will be measured using the abbreviated eight-item version of the PTSD Checklist for DSM-5 (PCL-5, Price et al., 2016). Items are rated on a five-point scale from 0 to 4 and add up to a total severity score of 32. The previous version of the PCL (PCL-6) (Lang & Stein, 2005) that was based on the diagnostic criteria of DSM-IV has shown good psychometric properties and has been tested in diverse cultural settings.

In addition to CMD symptomatology, self-defined problems and symptoms will be measured using the Psychological Outcome Profiles instrument (PSYCHLOPS, Ashworth et al., 2004), which consists of four questions. It contains three domains: problems (2 questions), function (1 question), and wellbeing (1 question). Participants are asked to give free-text responses to the problem and function domains. Responses are scored on an ordinal six-point scale producing a maximum score of 20 (5 points per question). The pre- and post-therapy versions of PSYCHLOPS consist of the same four questions, but the post-therapy version adds an overall evaluation question (determining self-rated outcome ranging from "much better" to "much worse"). The PSYCHLOPS has been validated in primary care populations across several countries (e.g., Czachowski et al., 2011), and has been used in WHO studies in Pakistan, Kenya, and Uganda.

Mediators

The German questionnaire «Fragebogen zur Erhebung von Kontrollüberzeugungen zu Krankheit und Gesundheit» (KKG, Lohaus & Schmitt, 1989) measures three dimensions, i.e.,

beliefs in internal, social–external, and fatalistic–external illness-related locus of control. Each dimension is assessed by seven items, with response options ranging from 1 ("not at all") to 6 ("fully agree"); dimensional scores range from 7 to 42. Higher scores indicate greater conviction regarding a particular locus of control dimension. This questionnaire was translated and back-translated for the purpose of this study. The comprehensibility of this measure was checked in a pilot phase and found to be acceptable.

The Illness Perception Questionnaire Revised (IPQ-R, Moss-Morris et al., 2002) measures different kinds of beliefs about an illness (e.g., about its course, consequences, personal control, treatment control, etc.). We will use only the second part, which includes assumptions about causes (i.e., personal attributions, risk factors, immunity, accidents, or chance).

Furthermore, we will measure working alliance with Hap-pas-Hapi using the Working Alliance Inventory (WAI) for guided Internet interventions (Gomez Penedo et al., 2019). The original version of the WAI contains 36 items on the working alliance in face-to-face therapies (Munder et al., 2010). The items can be summarised in three sub-scales: task, goals, and bond. The first two scales measure to what extent a patient thinks he agrees with the therapist on the tasks and the goals of the therapy, whereas the bond scale measures the affective bond with the therapy. The WAI was adapted for guided internet-interventions (Gomez Penedo et al., 2019). Items on task and goals were reformulated in a way that they reflect agreement with the online programme (as opposed to the therapist). An example item would be "The goals of the online program were in line with my goals." The bond scale of the WAI-I assesses the therapeutic relationship with an e-helper. As we will implement guidance on-demand only (see above), we will omit the bond scale for the present trial.

Other measures

Socio-demographic information, including sex, age, marital status, nationality, level of education, work, and time lived in the host country, will be assessed.

Acculturation will be measured using the Vancouver Index of Acculturation (VIA, Ryder et al., 2000), which assesses both identification with the culture of heritage and receiving culture as two independent dimensions. It contains 20 items that are rated on a scale from 1 ("strongly disagree") to 9 ("strongly agree"). This questionnaire was translated and back-translated for this study.

The original Client Satisfaction Questionnaire CSQ (Larsen et al., 1979) was designed to measure client satisfaction with mental health services. We will use the adapted version for internet-based interventions (Boss et al., 2016). Items are responded to on a 4-point Likert scale.

Table 1. Measures and assessment time points.

	Self-Screening	Pre-assessment	Weekly measures	End of introduction and end of session 1	Before starting session 3	Post-assessment	Follow-up assessment
Psychological distress (K10)	X		X				
Psychological distress (HSCL-25)		X			X	X	X
Exclusion criteria (age, country of residence, suicidal plans)	X						
Functioning (WHODAS 2.0)		X				X	X
Subjective well-being (WHO-5)		X				X	X
Post-traumatic stress (PCL-5, eight items version)		X				X	X

	Self-Screening	Pre-assessment	Weekly measures	End of introduction and end of session 1	Before starting session 3	Post-assessment	Follow-up assessment
Self-defined psychosocial problems (PSYCHLOPS)		X				X	X
Health beliefs (KKG, IPQ-R)		X			X	X	X
Working alliance (WAI-R)				X		X	
Acculturation (VIA)		X					
User satisfaction						X	X

Note: K10 = Kessler Psychological Distress Scale; HSCL-25 = Hopkins Symptom Checklist; WHODAS 2.0 = WHO Disability Assessment Schedule; WHO-5 = WHO Well-being Index; PCL-5 = PTSD Checklist for DSM-5; PSYCHLOPS = Psychological Outcome Profiles instrument; KKG = Fragebogen zur Erhebung von Kontrollüberzeugungen zu Krankheit und Gesundheit [Questionnaire to assess control attributions related to health and illness]; IPQ-R = Illness Perception Questionnaire Revised; WAI-R = Working Alliance Inventory Revised; VIA = Vancouver Index of Acculturation.

Statistical analysis

To compare the two treatment groups at baseline, t-tests will be conducted for continuous variables (e.g., symptom severity) and Chi-squared test for categorical ones (e.g., gender, marital status).

To estimate the effect of cultural adaptation on the first primary outcome (symptom reduction), a linear pre-post model will be employed for the primary outcome (HSCL-25) and the mean difference between the two treatment arms together with its 95% confidence interval will be derived. A covariate-adjusted model of the primary outcome will also be performed by adding pre-specified covariates at baseline (gender, age, education, and severity of symptoms) into the above model. Furthermore, a linear mixed model will be estimated. To test the mediator model (i.e., health beliefs mediating the relationship between cultural adaptation and treatment efficacy), the statistical recommendations by Lemmens et al. (2016) will be followed, using bootstrapping (Preacher & Hayes, 2004) (MacKinnon et al., 2006) for examining the indirect effect. Finally, a covariate-adjusted model of the primary outcome will be performed by adding the level of acculturation (VIA) into the above model as a moderator.

The second primary outcome (adherence) will be assessed by comparing the proportion of participants in each arm who completed at least 3 out of 5 sessions, reporting the difference as well as the 95%-confidence interval. Additionally, the mean number of completed sessions in each arm will be analysed (difference and 95%-confidence interval) as a sensitivity analysis. Based on a logistic regression, the mediator model will assess the effect of cultural adaptions on study adherence (at least 3 out of 5 sessions completed) mediated through working alliance (WAI-R) with the program measured after session 1, where most adaptions are implemented. The same statistical recommendations and bootstrapping will be used as for the mediation analysis of the first primary outcome.

Separate linear pre-post models will be carried out for analysing the following clinical outcomes: functioning (WHODAS), well-being (WHO-5), posttraumatic stress reactions (PCL-5), and self-identified symptoms (PSYCHLOPS).

Ethics

The project was submitted to the Ethics Committee of the Canton of Zürich (2020-00049), who declared that they were not responsible since the study does not fall within the scope of the Human Research Act. Thereafter, it was submitted to the Ethics Committee of the Faculty of Arts and Social Sciences at the University of Zurich (decision pending at the time of submission of the paper). In addition, the study was approved as an Amendment of the STRENGTHS study by the Ethics Committee at the Department of Education and Psychology, FU Berlin (161_2/2017).

Discussion

In cultural adaptation literature, empirical evidence on different levels of adaptation is lacking, and experimental studies are scarce. The present study aims to deliver such evidence as a starting point for future studies. For this purpose, two levels of cultural adaptation – surface vs. deep structure (Resnicow et al., 1999) – of an online self-help programme for the treatment of psychological distress will be compared in a randomized controlled trial. Evidence indicates that a higher level of adaptation of such self-help programmes is associated with a higher effect size of the intervention (Harper Shehadeh et al., 2016). However, direct comparisons of different levels of cultural adaptation are scarce, and so far limited to face-to-face interventions (Hall et al., 2016). In addition, evidence showed that adapting the "illness myth", i.e., the explanatory model, is associated with higher effect sizes of adapted interventions (Benish et al., 2011). Based on this evidence, we expect that the deep structure adaptation done in this study will increase the acceptability and efficacy of Hap-pas-Hapi.

In a new conceptual framework, Heim and Kohrt (2019) suggest using cultural concepts of distress (CCD), i.e., idioms of distress and explanatory models, as a pivotal point for cultural adaptation of psychological interventions. In this study, the target populations' CCD were examined in an ethnopsychological study (Shala, Morina, Salis Gross, et al., 2020). This study revealed specific idioms of distress and, in particular, fatalistic health beliefs, i.e., the assumption that human suffering is part of normal life and has to be endured with patience. Such fatalistic beliefs have been reported in different cultural groups, e.g., among Syrian displaced people (Hassan et al., 2015). We will use a specific intervention that has been developed and pilot-tested (Reich et al., 2019) to address such fatalistic beliefs. Thus, this study does not only compare two different levels of cultural adaptation but will also test a mediation model with a clear hypothesis on the mechanisms of action to explain the higher acceptance and effect size of the deep structure adaptation. Methodologically rigorous studies on mechanisms of action in psychological interventions are scarce (Lemmens et al., 2016).

Transparent reporting systems are needed in order to enhance the validity of results in cultural adaptation research. Only very few studies in cultural adaptation research have systematically described the adaptations that were made to make sure the intervention is relevant and acceptable for the target population (e.g., Abi Ramia et al., 2018). The cultural adaptions done for Hap-pas-Hapi were documented in a standardised reporting system to make sure they are transparent and replicable (Shala, Morina, Burchert, et al., 2020).

This study has several limitations. First, several adaptations were made at the same time. If our hypothesis is confirmed, it will not be possible to draw conclusions on the effect of individual modifications on the positive outcomes. For a better understanding of the respective relevance of individual modifications, future studies may use more innovative designs than the classic randomised controlled trial, e.g., by applying the Multiphase Optimisation Strategy (Collins, 2018). However, the present study provides first empirical insights to test whether a deep structure adaptation makes a difference at all. More

sophisticated methods can be used once we have empirical indication that such adaptations make a difference. Second, first studies with the Step-by-Step programme showed a relatively high drop-out rate (Harper Shehadeh et al., 2020). Improvements to the intervention that have been done prior to starting the definitive trials in Lebanon and the STRENGHTS will hopefully contribute to decreased drop-out rates. With the adaptations done in this study, we expect to further decrease intervention attrition, which is part of the research questions that we are aiming to address. A third limitation is the fact that the programme is offered in Albanian language only. Albanian-speaking migrants in Switzerland and Germany, especially the ones in the second and third generation, might be more familiar with German language. However, due to financial restrictions, it was not possible to add another translation of the programme. Fourth, an important limitation concerns the questionnaires used in this study. Very few validated questionnaires exist in Albanian language, and we had to translate and back-translate several questionnaires ourselves. The translations were done following gold-standard translation and back-translation procedures, and comprehensibility was pilot tested. However, it would have been beyond the scope of this study to validate these translated questionnaires. For future projects, we aim to start validating our translations, to render research on cultural adaptation for this target group more valid. As a final limitation, it is important to consider that particularly first-generation immigrants may have limited media-literacy. Some users in the pilot study by Reich et al. (2019) needed assistance using a computer and the web-based intervention. This limitation will be addressed by e-helpers, who will provide support to users who have any question related to the use of Hap-pas-Hapi. Despite these limitations, this theory-driven, methodologically sound study will contribute to advance knowledge on the cultural adaptation of psychological interventions.

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