BMJ Open

Evaluating a stepped care model of psychological support for adults affected by adversity: study protocol for a randomised controlled trial in Jordan

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To cite: Keyan D, Habashneh R, Akhtar A, *et al*. Evaluating a stepped care model of psychological support for adults affected by adversity: study protocol for a randomised controlled trial in Jordan. *BMJ Open* 2024;**14**:e078091. doi:10.1136/bmjopen-2023-078091

► Prepublication history and additional supplemental material for this paper are available online. To view these files, please visit the journal online (https://doi.org/10.1136/bmjopen-2023-078091).

Received 24 July 2023
Accepted 16 January 2024

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ABSTRACT

Background The burden of common mental disorders in low and middle-income countries (LMICs) is growing with little known about how to allocate limited resources to reach the greatest number of people undergoing instances of significant psychological distress. We present a study protocol for a multicentre, parallel-group, superiority, randomised controlled trial.

Methods and analysis Adults with significant psychological distress (K10 score ≥20) will be randomised to receive a stepped care programme involving a self-guided course (*Doing What Matters*) followed by a more intensive group programme (*Problem Management Plus*) or the self-guided course alone, both of which will take place in addition to enhanced treatment as usual comprising of a follow-up referral session to available services within the community. We will include 800 participants. An intent-to-treat and completer analysis will explore the impact of the stepped model of care on anxiety and depression symptoms (as measured by the Hopkins Symptom Checklist; HSCL-25) at 24 weeks from baseline. Secondary outcomes include positive psychological well-being, agency, changes in patient-identified problems, quality of life and cost-effectiveness. Linear mixed models will be used to assess the differential impact of the conditions over time. Analyses will focus on the primary outcome (HSCL-25) and secondary outcomes (agency subscale, WHO Well-Being Index, WHO Disability Assessment Schedule V.2.0, EQ-5D, Psychological Outcomes Profiles Scale) for both conditions, with the main outcome time point being the 3-month follow-up, relative to baseline.

Ethics and dissemination This will be the first randomised controlled trial to assess the benefits of a stepped model of care to addressing psychological distress in a LMIC setting. Results will provide important insights for managing limited resources to mental healthcare in these settings and will be accordingly disseminated to service providers and organisations via professional training and meetings, and via publication in relevant journals and conference presentations. We will also present these findings to the Jordanian Ministry of Health, where this institute will guide us on the most appropriate format for communication of findings, including written reports, verbal presentations and/or brochures. Ethical approval was obtained from the University of Jordan School of Nursing Research Ethics Committee (number: PF.22.10).

Trial registration number ACTRN12621000189820p; Australian New Zealand Clinical Trials Registry.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This is the first trial to investigate the relative efficacy of a stepped care programme compared with a single intervention in a low and middle-income country (LMIC) setting; it will provide clinicians and researchers with important information about this model of care.
⇒ The methodology aims to identify whether a stepped care framework is more efficacious and cost-effective in promoting better mental healthcare for people in LMICs.
⇒ The comprehensive list of questionnaires will provide important information relating to psychological well-being, including symptom and quality of life/functioning outcomes.
⇒ A large and diverse study sample of service users residing in Jordan will be invited to participate in this trial.

BACKGROUND

The rise in humanitarian crises across low and middle-income country (LMIC) settings has left many people in highly volatile and stressful circumstances, and in turn at risk of developing common mental disorders.[1] For example, Jordan is a small middle-income country within the Middle East whose social and economic climate has been heavily impacted by ongoing conflicts in the neighbouring Arab regions. In particular, the resettlement of refugee populations from neighbouring regions, rising unemployment and poverty rates have together coincided with high rates of psychological distress in recent times.[2 3] Despite this high need for mental healthcare in such settings,

many who require support do not receive adequate and accessible care; evidence from the World Mental Health Survey found that whereas 36.3% of respondents in high-income countries in the World Mental Health Survey who reported an anxiety disorder received help, only 13% of those in LMICs reported receiving assistance.[4] While low mental health literacy and significant stigma pose as considerable barriers to healthcare access, inadequate numbers of mental health specialists and insufficient budgets for mental healthcare also maintain the gap in availability of treatment. In Jordan, for example, most available support for mental health exists within long-stay psychiatric hospital facilities,[5] where specialist mental health support is often directed towards severe instances of mental illness (eg, psychoses, suicide and self-harm risk), and this is a pattern not uncommon across the Middle East.[6 7] Accordingly, there is a considerable gap in needing to provide care to those with significant instances of common psychological disorders, such as anxiety and depression. The growing challenge is to be able to ease the burden of common mental health problems, but with a focus to help the greatest number of people with relatively limited resources.

Task shifting involves the redistribution of tasks among healthcare teams with a focus to use resources more efficiently within a given setting.[8] Here, non-specialist providers are used to deliver evidence-based psychological interventions and this is one initiative geared towards addressing this treatment gap. There is evidence to suggest that dissemination of such programmes in LMICs that employ task shifting approaches has shown moderate effects in outcomes for common mental health problems.[9] To this end, the options available in addressing common mental health problems through task shifting initiatives have drastically increased over the past decade. *Self-Help Plus* (SH+) is one such lay provider disseminated intervention involving large groups of individuals (up to 30 people) assisted through an illustration-based workbook accompanied with audio-guided exercises. Developed by the WHO, SH+ was designed to reach the maximum number of people at very low costs. The programme teaches stress management skills in a way that promotes one's psychological flexibility based on principles of mindfulness.[10] As a low-intensity programme, SH+ has evidenced small to moderate effects in reducing psychological distress (Effect Size of 0.2–0.6[11]), but with evidence also suggesting that a significant number (39%) do not respond to the intervention,[12] and other studies evidencing an absence of meaningful change from SH+.[13 14] It is worth contextualising these findings within the context of its intended use as an initial early intervention rather than as standalone care.[10] A recent adaptation of this programme by the WHO, *Doing What Matters* (DWM), has been designed for individual delivery (vs group) across a 5-week period, during which time participants follow exercises outlined in an illustrated self-help booklet and are supported with 15 min phone calls each week from a lay helper.[15] The comparative effectiveness of DWM has yet to be investigated in a full-scale trial. In contrast, *Problem Management Plus* (PM+) is a standalone intervention also developed by the WHO for use during crises and adversity. Specifically, it is facilitator led (vs self-help) in either individual or small-group formats and involves teaching evidence-based techniques, including stress management, problem solving, behavioural activation and social support enhancement.[16] PM+ has evidenced relative stronger effects in terms of reductions of psychological distress and increases in well-being.[17–19]

Despite the promise of these varying programmes, there is currently limited understanding of who will respond to low-intensity self-help interventions (eg, SH+ or DWM), and whom should be prescribed more intensive programmes (eg, PM+). Implementing psychological support through a stepped care model is one approach to addressing this significant public health issue. With a *doing more with less* focus, stepped care approaches to mental healthcare have been shown to be cost-effective and increasingly used in high-income settings to treat common mental health disorders such as depression and anxiety.[20 21] The premise here is that when an individual does not reach a target milestone following a low-intensity intervention, they are stepped up and referred to more intense interventions. There have been stepped care initiatives in LMICs; however, these have been limited to providing different levels of non-specialist counselling, psychotherapy and antidepressant medication, depending on the person's mental health needs.[22] To date, there are no studies of the relative efficacy of a stepped care programme compared with a single intervention. This study aims to fill this gap. The current study's aims are twofold: (1) assess the effectiveness of two scalable WHO psychological interventions that were locally adapted to the Jordanian context for adults in psychological distress and (2) evaluate the success of this implementation in a manner that could inform future scalability.[23]

Accordingly, the current study will initially provide adults in Jordan reporting psychological distress with DWM. Those who report persistent distress following this intervention will be randomised to receive either PM+ and enhanced treatment as usual (ETAU) or ETAU alone. This design aims to identify whether a stepped care framework is more efficacious and cost-effective in promoting better mental healthcare for people in LMICs. To our knowledge, this study will be the first to inform how stepped care interventions may perform in settings affected by ongoing humanitarian crises.

METHODS

Design

A two-arm, single blind, individually randomised treatment trial will be conducted, comparing a self-guided intervention (DWM) followed by a group intervention (PM+) or a follow-up referral session (ETAU) for those who still report significant clinical symptoms of distress (as reported by the Kessler-10 cut-off of ≥20). Outcomes

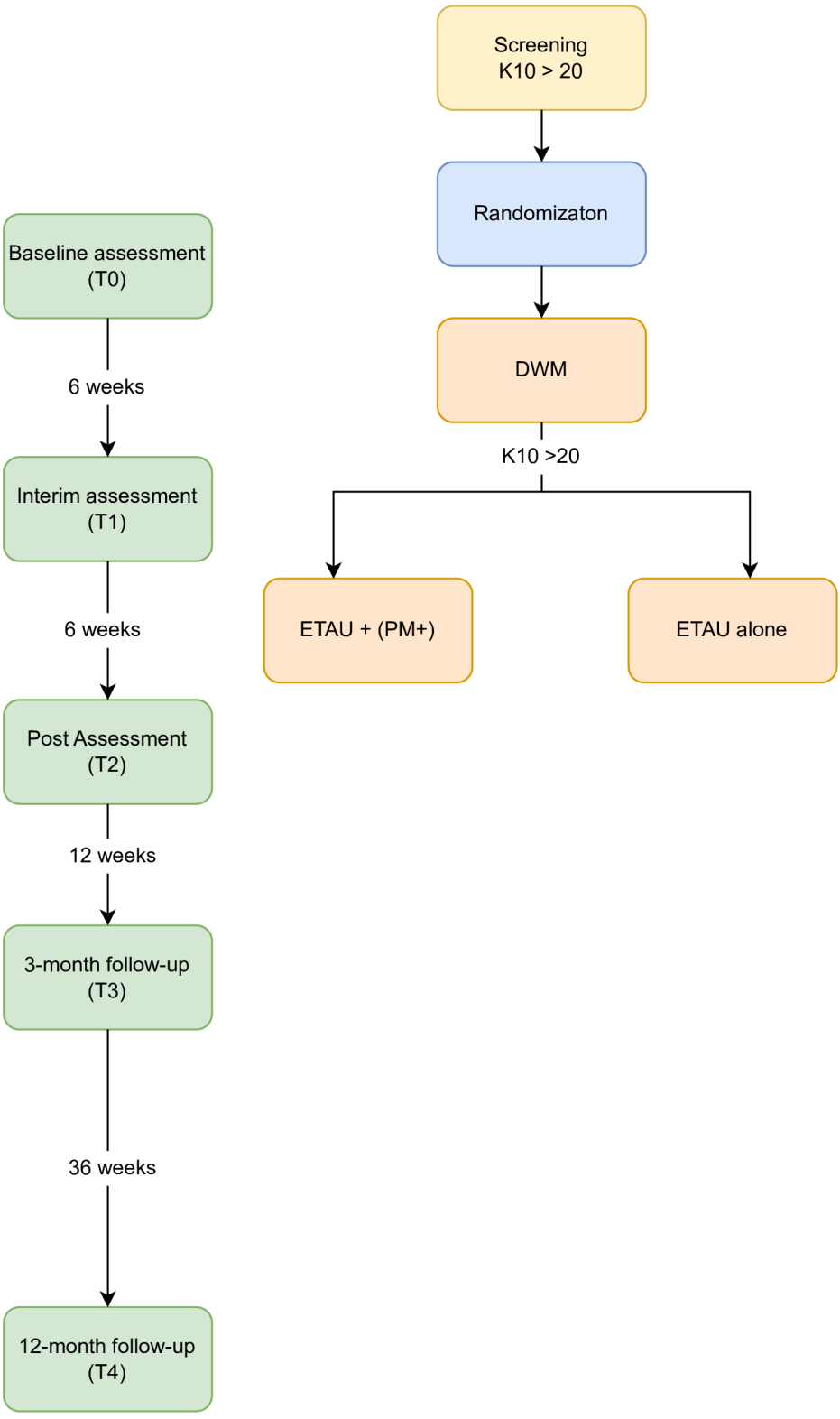

Figure 1 Study flow diagram. DWM, Doing What Matters; ETAU, enhanced treatment as usual; PM+, Problem Management Plus.

for clinical effectiveness will be assessed baseline (T0), mid-point (T1), postintervention (T2), 3-month postintervention (T3) and twelve-month post intervention (T4) follow-ups, where the primary outcome will be set as T3 (see figure 1). The standard protocol items: Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) is outlined in figure 1. The completed SPIRIT checklist is available in online supplemental file 1. This trial was prospectively registered on 22 February 2021 (ACTRN12621000189820p) and received local

ethical approval from the University of Jordan (number: PF.22.10). The planned dates for this study are May 2023 to March 2025.

Aims and hypotheses

This trial aims to assess the effectiveness of a stepped model of care for psychological distress in adults affected by adversity in Jordan. The primary aim is to assess whether this model of care can improve the mental health in those who do not sufficiently respond to an initial self-guided programme (ie, DWM), where a more intensive programme is directed to them (ie, PM+). A secondary aim is to assess quality of life, consumer-rated changes in problems after intervention and cost-effectiveness. Further secondary investigation will assess the potential moderators (eg, past-traumatic exposures) and mediators (eg, perceived agency) to clinical outcomes. We hypothesise that improvement in psychological distress and quality of life outcomes will be larger among participants in the stepped care arm relative to a self-guided intervention alone arm.

The study will be conducted across preidentified governorates in Jordan, including Amman, Karak and Irbid. This study will be implemented by the Institute for Family Health (IFH), a national non-governmental organisation in Jordan. Participants will be recruited by interviewing one adult from the household of community lists of people engaging with IFH services in the preidentified governorates. Informed consent will be obtained using a two-step procedure: (1) participants will be provided a verbal overview of the programme over the phone. After confirming their interest and obtaining verbal consent over the phone during this first contact, assessors will conduct screening to explore whether potential participants meet inclusion criteria for the study; (2) written consent will be subsequently obtained from participants in person (ie, second contact) after they have been able to consider the programme over a number of days. This consent form is available in online supplemental file 2. Inclusion criteria are (a) Jordanians or refugees residing in Jordan aged at least 18 years, (b) present with psychological distress (Kessler Distress Scale 10 score ≥20[24]) and (c) reported sufficient literacy in the Arabic language. Exclusion criteria are (a) imminent plans of suicide, (b) psychotic disorders, (c) severe cognitive impairment, (d) identification of risk of the person's safety (eg, partner violence), (d) plans to return to Syria in the next 12 months or (e) no access to a telephone. If participants are determined to be eligible, they will be administered the baseline assessment questionnaires (T0). See table 1 for an overview of the study flowchart.

Screening assessments

Psychological distress will be measured through the Kessler Distress Scae-10 (K-10).[25] Ten items related to general well-being and distress are rated on a 5-point scale (range 0 to 50; higher scores indicate higher levels of psychological distress), where a cut-off of 20[26] will be used to screen individuals with psychological distress. The K-10 has been used as a screener to accurately detect common mental disorders.[24] Imminent risk of suicide will be assessed using a brief 3-item questionnaire, where individuals will be asked if they endorse the presence of ideation and/or actions over the past month, and future plans. Participants excluded will be referred to appropriate services through IFH. If participants are not selected because they score below the K-10, they will be provided with feedback and reasons for exclusion from the study will be explained to them.

Randomisation

Randomisation will occur following completion of T0 assessment. Computer-generated randomisation sequences will be used to allocate participants to either stepped care or self-guided intervention alone arm on a 1:1 allocation basis. To ensure adequate numbers by demographic, separate randomisation sequences will be created for each site, and within this, separate sequences will be used to create strata for Jordanian and Other (including Syrian, Palestinian, Iraqi or other refugees) participants (at a ratio of 6:4). Blocking will be used to ensure that the allocation ratio is maintained, and this will involve block sizes of 10. The project coordinator will inform participants of their randomised allocation at T1. Assessors who are blind to participants' condition will conduct assessments across T0–T4. Assessors will be situated in a separate location in Amman from those providing the interventions, thereby reducing the likelihood of contaminating randomisation. Checks of blinding will be assessed by having assessors guess the condition of the participant at each assessment.

Interventions

DWM in times of stress

DWM is a guided self-management course consisting of an illustrated booklet with strategies to manage stress based on acceptance and commitment therapy techniques.[27] It is structured such that participants can work through these strategies within a 5-week period at a self-paced manner. Chapters focus on management of psychological distress through (1) 'grounding' (slow breathing, present moment awareness); (2) 'unhooking' (noticing and naming overwhelming feelings and refocusing on present activities); (3) 'making room' (strengthening the ability to accommodate strong feelings without being overwhelmed by them); (4) identifying personal values and living in consistence with these values and (5) being kind to oneself and others. Along with the booklet, participants are provided with audio exercises to support practice. A cognitive interviewing approach was taken to culturally adapt the booklet (including illustrations, wording of content in written and audio format), and this was done by mental health experts, consumers and administrators in Amman. Responses were analysed to locally adapt and tailor the intervention for adults in Jordan, following similar studies.[28] To support use of

Table 1 Participant timeline and assessments

	Study period					
	Screening	Baseline	Interim	Postintervention	3-month follow-up	12-month follow-up
Timepoint:		T0	T1 (6 weeks)	T2 (12 weeks since T0)	T3 (24 weeks since T0)	T4 (60 weeks since T0)
Eligibility screen K10	X					
Informed consent	X					
Randomisation		X				
Interventions:						
DWM/ETAU		←	—	→		
PM+/ETAU			←	—	→	
Assessments:						
Sociodemographic variables (WHODAS A1–A5)	X					
K10	X		X			
Depression and Anxiety (HSCL-25)		X		X	X	X
Agency subscale		X	X	X	X	X
Wellbeing (WHO-5)		X		X	X	X
Health and Disability (WHODAS 2.0)		X		X	X	X
Quality of Life (EQ-5D-5L)		X		X	X	X
Costs of Programme Implementation (CSRI)		X		X	X	X
Self-identified problems (PSYCHLOPS)		X		X	X	X
Lifetime Traumatic Experiences (LEC-27)		X				

DWM, Doing What Matters; EQ-5D-5L, Euro Quality of Life (5-level version) questionnaire; ETAU, enhanced treatment as usual; HSCL-25, Hopkins Symptom Checklist; LEC-27, Life Events Checklist; PM+, Problem Management Plus; PSYCHLOPS, Psychological Outcomes Profiles Scale; WHO-5, WHO Well-Being Index; WHODAS 2.0, WHO Disability Assessment Schedule V.2.0.

DWM strategies, participants will be supported by a lay helper who will conduct three phone calls of 15 min duration throughout the 5 weeks. These calls will be provided at prespecified time points, including weeks 1, 3 and 5, with flexibility for movement dependent on participant circumstances (eg, postponement of call due to illness). Through these phone calls, participants will be reminded to engage with strategies and receive support to trouble shoot any problems relating to their use.

Problem Management Plus

PM+ is a brief psychological intervention based on cognitive behavioural therapy techniques and has been previously adapted for and tested in a Jordanian context.[28 29] The programme includes motivational interviewing and psychoeducation, stress management (ie, slow diagrammatic breathing), structured problem-solving, behavioural activation, strengthening social supports and relapse prevention. Group PM+ will be delivered across 5 weekly sessions of 90 min duration in a group format of 8–10 participants.

Enhanced treatment as usual

Both stepped care-guided and the self-guided course alone arms will receive a single follow-up referral session over the phone involving information about available services within the community.

Outcome measures

T1 assessments will be scheduled within 1 week of the final DWM helper support call (ie, 6 weeks after T0), T2 assessments will be scheduled 6 weeks following T1 (ie, 12 weeks following T0), T3 assessments will be scheduled 12 weeks following T2 (ie, 24 weeks following T0) and T4 assessments will be conducted at 36 weeks following T3 (ie, 60 weeks following T0). All instruments have been translated into simple, formal Arabic that can be understood by participants in the region (ie, Jordanians and Syrians) in line with recommendations for cross-cultural research.[30] Outcome assessments will be administered individually over the phone by trained assessors using Qualtrics software on smart tablets. Prior to this, assessors will receive training (combination of didactic and role playing of required skills) on the purpose of psychosocial assessments for research studies, including information on research ethics, sensitive interviewing and obtaining consent, study procedures and risk of bias in collecting quantitative data. Additionally, they will be trained in managing participant distress, adverse event

(AE) reporting and data management. The research programme coordinator will monitor the assessors' competency through regular supervision.

Primary outcome

The primary outcome will be anxiety and depression symptoms as measured using the Hopkins Symptom Checklist-25 (HSCL-25[31]) that is a cross culturally validated 25-item questionnaire. The HSCL-25 is rated on a 4-point scale (with higher scores indicating increased severity) has demonstrated good reliability and sound consistency across culturally distinct populations such as Asia[29 32] and Eastern Africa.[33]

Secondary outcomes

WHO Well-Being Index (WHO-5) will be used to assess positive psychological well-being as a measure of responsiveness to the stepped care intervention. The WHO-5 consists of five items on which participants rate the extent to which they endorse each item over the past 14 days on a 6-point Likert scale (with higher scores indicating more positive well-being). This measure has been used to detect states of positive mood, interest and energy that as part of assessment for depression severity.[34]

The WHO Disability Assessment Schedule V.2.0 (WHODAS V.2.0)[35] will be used to collect health and disability information. This is a generic instrument that assesses difficulties people may experience as a result of illness across six domains (ie, cognition, mobility, self-care, getting along, life activities and participation) during the past 30 days. Difficulties are scored on a 5-point Likert scale, where higher scores indicate worse functional impairment. The WHODAS 12-item interviewer version will be administered and this has been validated in different cultural contexts. Further sociodemographic information will be collected through WHODAS questions A1–A5. A second measure of current state of health will be indexed using the EURO-QoL-5D-5L.[36] This is a reliable and responsive measure of an individual's current health across five domains (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) and five levels of functioning (no problems, slight problems, moderate problems, severe problems and unable to/extreme problems). Participants also rate their overall health using a visual analogue scale. The EQ-5D has been cross-culturally validated.[37]

Changes in personally identified problems will be assessed using the Psychological Outcomes Profiles Scale (PSYCHLOPS[38]), which are not otherwise assessed using standardised symptom measures. The PSYCHLOPS consists of four questions across three domains: problems, function and well-being. At baseline, participants are asked to describe their main problems (two questions) and impact on function (one question) in free text format and score it on an ordinal 6-point scale. The well-being domain does not have an idiographic component and is rated on an ordinal scale as above. At postintervention timepoints, participants are asked to rescore their endorsement to the self-identified problems. The PSYCHLOPS has been validated in primary care populations across several countries.[29 39 40]

Cost-effectiveness of the stepped care intervention for mental healthcare will be assessed using the Client Service Receipt Inventory (CSRI). This measure has been developed for collection of data on service utilisation and related characteristics for people with mental disorders. The CSRI has been cross-culturally validated.[41]

Participants' perceived agency will be assessed using the agency subscale of the State Hope Scale.[42] Participants rate the extent to which they endorse items on an 8-point Likert scale. The agency subscale consists of three items that relate to an individual's propensity to engage in goal-directed thinking and purse-related actions. The agency subscale has been validated for use following brief behaviour change interventions.[43] This measure will be used as a secondary outcome and possible mediator of intervention effects in the current trial.

Participants' previous exposure to potentially traumatic events will be screened using the Life Events Checklist (LEC).[44] The LEC is a widely used list of 16 experienced or witnessed traumatic events (eg, rape, serious injury, combat exposure or the sudden death of a loved one). Based on qualitative assessments in prior trials, this 16-item list was adapted to consist of 27 items,[29] and this later version will be used to measure traumatic exposure as a demographic characteristic and possible moderator of intervention effects in the current trial.

Facilitator selection, training and supervision

The guidance model for the DWM intervention will be delivered by six lay helpers, recruited by IFH. They will receive 5 days of training in basic counselling skills, delivery of DWM strategies, remote support and self-care. Following training, participants will engage with pilot participants to practice learnt skills. Similarly, the PM+ intervention will be delivered by trained facilitators who will be employed at IFH. They will receive 8 days of training in basic counselling skills, delivery of PM+ strategies and group facilitation skills, followed by conduct of two practice cases. Both DWM and PM+ facilitators will receive weekly group supervision by trained clinical psychologists. In the event, a practice cycle cannot be conducted, a role play competency assessment will be conducted. These will be used to assess facilitator competency prior to the commencement of interventions for the trial. All helpers and facilitators will receive regular weekly supervision remotely by video teleconferencing with a clinical psychologist (HE-D) to ensure treatment adherence and provide regular support to helpers and facilitators.

ETAU facilitators will receive a 1-day training in delivering scripted sessions for accessing external referrals, basic counselling skills and self-care. A role play competency assessment will be conducted after the training. ETAU facilitators will receive one group supervision mid-way through the conduct of the intervention phase.

Additionally, debrief and feedback sessions will be conducted in a group format at the end of the intervention phase.

Patient and public involvement

We conducted an initial planning meeting in March 2022 with key stakeholder groups to develop the design of the stepped care intervention. During this time, we gathered information on needs of prospective participants, service providers and the partnering organisation (ie, IFH). As part of the cultural adaptation processes, we conducted focus groups and gathered key data on participants' perceptions of the proposed intervention content, including audio and visual materials. The design of the trial and related research protocol were presented to the Ministry of Planning in Jordan for review and feedback obtained on the nature of the study.

Blinding

Participants and programme managers will not be blind to participant allocation. The research assistant team will remain blind to the intervention allocation throughout the trial and will operate independently. All assessors have been trained in the importance of maintaining blinding. Prior to conducting each of the outcome assessments (ie, T1–T4), all participants will be informed of the importance of not revealing their allocation to the assessors. At the end of each T1–T4 assessments, assessors will provide a guess as to which treatment the participant received, where these guesses will be expected to be no greater than chance. Researchers conducting the statistical analyses will be blind to treatment condition.

Sample size

The sample size calculation for this treatment trial was based on a two-group comparison of the HSCL-25 score at T3. Power calculations to detect a small to moderate effect size based on previous studies indicated that a minimum sample size of 128 completers per group at the stepped care stage (power=0.95, alpha=0.05, two sided), allowing for 40% non-response to DWM, and subsequent 160 randomised to PM+or ETAU; with estimated 20% attrition at follow-up will in turn require an initial enrolment of 800 participants.

Statistical analysis plan

Both intent-to-treat and completer analysis will be carried for all quantitative data.

Comparability between stepped care and self-guided intervention alone conditions on baseline characteristics will be analysed using multiple planned comparisons for continuous measures and χ^2 tests for categorical variables. Differential change over time between conditions will be assessed using linear mixed models that accommodate missing data at subsequent assessments and provides differential slopes of trajectories between conditions. Analyses will focus on the primary outcome (HSCL-25) and secondary outcomes (agency subscale, WHO-5, WHODAS 2.0, EQ-5D, PSYCHLOPS) for conditions, with the main outcome time point being the 3-month follow-up, relative to baseline. To assess the robustness of this statistical approach, we will conduct subsequent analyses, including only participants who complete the 3-month follow-up. Secondary exploratory analyses will assess the differential impact of the intervention among refugees with probable clinically significant problems relating to anxiety or depression on the HSCL (defined as mean item score ≥2 on anxiety or ≥2.1 on depression subscales). Additional secondary analyses will explore the roles of gender, perceived agency and exposure to traumatic events (LEC) on outcomes. Two-tailed tests will be reported with a significance level of $p<0.05$ for all analyses. Separate cost-effectiveness analyses will be conducted and reported following this trial.

Ethics and dissemination

Ethics

This project has been approved by the University of Jordan School of Nursing Research Ethics Committee (number: PF.22.10). All trial studies were performed in accordance with relevant guidelines and recommendations (as per the University of Jordan Research Ethics Committee regulations).

Data management and trial monitoring

The project manager and coordinator comprise of the day-to-day study team and will monitor the study procedures on an ongoing basis and act as data monitors for AEs reporting. The chief investigators, project coordinator and project manager will meet on a weekly basis to monitor ongoing progress. An AE is considered to be any undesirable experience occurring to a participant during the study, whether or not considered related to the research procedure. We will monitor the occurrence of specific serious AEs (eg, suicide attempts, serious violence) and AEs (eg, injuries on the way to the intervention). Assessors, DWM helpers and PM+ facilitators will detect AEs during assessments and delivery of the interventions. In the event of immediate risk of harm, helpers/facilitators will contact one of the clinical supervisors to evaluate the situation and made informed clinical decisions (eg, contacting emergency department of the nearest hospital). In the absence of imminent risk, helpers/facilitators will be trained to address these situations and report to clinical supervisors after finishing the intervention session. All AEs will be recorded by the helpers/facilitators and reported to the programme coordinator, who in turn will inform study investigators. The principal investigator will refer all AEs to the local ethics committee in Jordan, including three local mental health service providers who will act as the Data Safety Monitoring Committee (DSMC). Three local mental health service providers who are independent of the trial team will consist of the DSMC. The DSMC will meet every 3 months to review progress and reporting methods. For the purpose of AE reporting, ongoing care and follow-up assessments, participants will be required to have their

identities known to the research implementation staff. All assessment data will be collected from online surveys (administered via Qualtrics data collection software) and will be imported into the SPSS statistical analysis database for data management and analysis. A research assistant team that is blind to intervention allocation throughout the trial will have access to all assessment data. A password-protected tablet will be used to collect data by assessors (T0 to T4). Qualtrics software will be used for the data collection. The data on the tablet will be synchronised and uploaded first on the Qualtrics Server. From this server, it will be downloaded and subsequently uploaded onto SPSS databases, where the data will be deidentified and stored confidentially. The data will be stored on a secure UNSW (i.e., the university instituion) housed data server, which is backed up every 24 hours. Following upload to the server, the data will no longer be available on the tablet. Tablets will be stored in locked IFH offices. The data are accessible on this server during the life of the particular trajectory and the data will remain accessible in an archive until a maximum upper limit of 7 years after completion of T4.

Audio recordings of helper phone call sessions will be collected in line with Consolidated Standards of Reporting Trials requirements for subsequent supervision and assessment of treatment fidelity. The UNSW Research Long Term Data Store Interface will be used to store data, and this will be accessed by the independent research team only.

Dissemination plan

Findings will be disseminated to service providers and organisations via professional training and meetings, and via publication in relevant journals and conference presentations. We will also present these findings to the Jordanian Ministry of Health, where this institute will guide us on the most appropriate format for communication of findings including written reports, verbal presentations and/or brochures.

DISCUSSION

This study will evaluate the role of a stepped care model in improving mental health outcomes for adults going through adversity in Jordan, a country that resembles many other LMICs in terms of the need for substantial assistance in enhancing its mental health system. The trial outline in this protocol is the first to assess the clinical effectiveness of a stepped care intervention in an LMIC setting. The extent to which effectiveness of the stepped model of care is demonstrated will shed important insights into how limited resources can be used to ease the burden of common mental disorders and bridge the gap in mental healthcare in LMICs. The findings are expected to inform future scalability efforts, guide policy decisions and ultimately improve the well-being of individuals experiencing psychological distress in Jordan and potentially other LMICs with limited resources.

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Contributors The authors alone are responsible for the views expressed in this article, which do not necessarily represent the views, decisions or policies of the institutions with which they are affiliated. All authors read and approved the final manuscript. LAD and RB, DK, AAk, AAb, ISA and RH were involved in drafting the study protocol for ethics review. H-ED and MF were involved in the preparatory work for trial implementation. Implementation of the trial will be conducted by DK and RH. Analyses will be conducted DK and RB. RB and DK will have access to final trial dataset.

Funding This study was supported by a r2hc (research for health in humanitarian crises) elrha grant. Grant number N/A.

Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer-reviewed.

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