PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Evaluating a Stepped Care Model for Psychological Support for Adults Affected by Adversity: Study Protocol for a Randomised Controlled Trial in Jordan
AUTHORS	Keyan, Dharani; Habashneh, Rand; Akhtar, Aemal; El-Dardery, Hafsa; Faroun, Muhannad; Abualhaija, Adnan; Aqel, Ibrahim Said; Dardas, Latefa; Bryant, Richard

VERSION 1 – REVIEW

REVIEWER	Calitri, Raff University of Exeter Medical School, Primary Care
REVIEW RETURNED	30-Aug-2023

GENERAL COMMENTS	This is an interesting and important trial exploring a stepped care model to improve psychological outcomes for those affected by adversity in Jordan. I enjoyed reading the protocol. It is generally well written and clear. There are small minor clarifications needed to the method, particularly around recruitment (to help us understand whether ethical considerations have been appropriately addressed) and trial monitoring and management. Please address the following: Page 3: Please define task-shifting approaches. Page 5: Please tell us where we can find the plan/results of the implementation evaluation. Currently you only state that it is “detailed elsewhere”. Page 5: You state “Following this intervention, those who report persistent distress will be randomised to receive either PM+ or enhanced usual care.” Should this say that those with persistent distress will be randomised to receive either PM+ and EUC or EUC alone? Page 6: It’s unclear whether T2-T4 time points refer to post randomisation or post intervention. Please clarify. Page 7: You state “Participants will be recruited by interviewing one adult from the household of community lists of people engaging with IFH services in the preidentified governorates”. Please clarify whether the contact with those using IFH services is a ‘cold’ call- or whether individuals have consented to be contacted about potential participation in the trial. Do individuals receive an information leaflet that they can review at their leisure and from which they can provide informed consent? Currently it seems that individuals decide to participate during the initial phone

	call, where they have had no time to consider the trial. Please clarify the process. Page 8: Randomisation: Please clarify how participants will be informed of their outcome allocation and who will do this. Page 9: You state “To support use of DWM strategies, participants will be supported by a lay helper who will conduct three phone calls of 15-minutes duration throughout the 5 weeks….” Please clarify whether these calls occur at pre-specified points (e.g., wk1, wk3, wk5; or is it based on individual circumstance?). Page 9: Enhanced Treatment as Usual (ETAU). Participants in both arms will receive a single follow-up referral session involving information about available services within the community. Please clarify the mode of delivery - is it face-to-face, online, telephone etc? Page 15: Trial monitoring: • Please clarify whether the DMSC are independent from the trial team. Also, as part of the progress review, are there any planned interim analyses to be conducted by the DMSC e.g., after T3, to determine early stopping (either for futility or positive efficacy)? • Please clarify whether there is an independent Trial Steering Committee who will oversee the trial? • Please outline who is part of the Trial Management Group (e.g., day-to-day study team) and the regularity of planned meetings. • Will there be PPI engagement throughout the course of the trial, will they input into study processes/review? Page 16: You state “Further details of data security and storage can be found in ethical protocols, which are available on request.” Please summarise your data security and storage plans in this protocol.

VERSION 1 – AUTHOR RESPONSE

Reviewer 1:

Comment:- Page 3: Please define task-shifting approaches.

Response: This has now been stated as follows:

Task shifting involves the redistribution of tasks among healthcare teams with a focus to use healthcare resources more efficiently within a given setting (8). Here, non-specialist providers are utilised to deliver evidence-based psychological interventions and this is one initiative towards addressing this treatment gap.

Comment:- Page 5: Please tell us where we can find the plan/results of the implementation evaluation. Currently you only state that it is “detailed elsewhere”.

Response: This unpublished work (manuscript in preparation) has now been cited

Comment:- Page 5: You state “Following this intervention, those who report persistent distress will be randomised to receive either PM+ or enhanced usual care.” Should this say that those with persistent distress will be randomised to receive either PM+ and EUC or EUC alone?

Response: This statement is revised as follows:

Those who report persistent distress following this intervention, will be randomised to receive either PM+ and enhanced treatment as usual (ETAU) or ETAU alone.

Comment:- Page 6: It’s unclear whether T2-T4 time points refer to post randomisation or post intervention. Please clarify.

Response: This is now clarified as follows:

Outcomes for clinical effectiveness will be assessed baseline (T0), mid-point (T1), post-intervention (T2), three-month post intervention (T3), and twelve-month post intervention (T4) follow-ups, where the primary outcome will be set as T3 (see Figure 1).

Comment:- Page 7: You state “Participants will be recruited by interviewing one adult from the household of community lists of people engaging with IFH services in the preidentified governorates”. Please clarify whether the contact with those using IFH services is a ‘cold’ call- or whether individuals have consented to be contacted about potential participation in the trial. Do individuals receive an information leaflet that they can review at their leisure and from which they can provide informed consent? Currently it seems that individuals decide to participate during the initial phone call, where they have had no time to consider the trial. Please clarify the process.

Response: Participants were provided with information verbally over the phone, and further written information was provided during the home visit. This is now detailed as follows:

(1) Participants will be provided an verbal overview of the program 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 (i.e., second contact) after they have been able to consider the program over a number of days.

Comment: Page 8: Randomisation: Please clarify how participants will be informed of their outcome allocation and who will do this.

Response: This now detailed as follows:

The project coordinator will inform participants of their randomized allocation at T1.

Comment: Page 9: You state “To support use of DWM strategies, participants will be supported by a lay helper who will conduct three phone calls of 15-minutes duration throughout the 5 weeks….” Please clarify whether these calls occur at pre-specified points (e.g., wk1, wk3, wk5; or is it

based on individual circumstance?).

Response: This is now detailed as follows:

These calls will be provided at prespecified time points including weeks 1, 3 and 5, with flexibility for movement dependent upon participant circumstances (e.g., postponement of call due to illness).

Comment: Page 9: Enhanced Treatment as Usual (ETAU). Participants in both arms will receive a single follow-up referral session involving information about available services within the community. Please clarify the mode of delivery - is it face-to-face, online, telephone etc?
Response: This information will be provided over the phone and is now detailed:

Both stepped care- 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.

Page 15: Trial monitoring:
Comment: Please clarify whether the DMSC are independent from the trial team. Also, as part of the progress review, are there any planned interim analyses to be conducted by the DMSC e.g., after T3, to determine early stopping (either for futility or positive efficacy)?

Response: The DSMC will be independent, and this has been detailed now in the manuscript. Interim analyses will not be conducted.

Comment: Please clarify whether there is an independent Trial Steering Committee who will oversee the trial?

Response: The trial was conducted by the Trial Steering committee, comprising the chief investigators of the trial**.**

Comment: Please outline who is part of the Trial Management Group (e.g., day-to-day study team) and the regularity of planned meetings.
Response: The trial management group meets on a weekly basis to monitor progress. This is now detailed as follows:

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 adverse events reporting. The chief investigators, project coordinator and project manager will meet on a weekly basis to monitor ongoing progress.

Comment: Will there be PPI engagement throughout the course of the trial, will they input into study processes/review?

Response: Yes, PPI will be incorporated in the study processes, and this is detailed in the Patient and public involvement section.

Comment: Page 16: You state “Further details of data security and storage can be found in ethical protocols, which are available on request.” Please summarise your data security and storage plans in this protocol.

Response: This information in now stated as follows:

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 synchronized 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 de-identified and stored confidentially. The data will be stored on a secure UNSW 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 is 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.

VERSION 2 – REVIEW

REVIEWER	Calitri, Raff University of Exeter Medical School, Primary Care
REVIEW RETURNED	02-Jan-2024

GENERAL COMMENTS	Thank you for fully addressing my comments and making the clarifications/updates to the manuscript. Good luck with the trial!

VERSION 2 – AUTHOR RESPONSE