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Self-help plus (SH+) for South Sudanese refugees in Uganda

Submission date	Recruitment status	[_] Prospectively registered
13/03/2017	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
27/04/2017	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
14/09/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Refugees are at risk of psychological distress and a range of mental disorders. The aim of this study is to test a new guided self-help intervention with South Sudanese refugee women in northern Uganda. The guided self-help intervention is designed to reduce high psychological distress in hard to access humanitarian populations.

Who can participate?
Women aged 18 or older who speak Juba Arabic, reside in the Rhino Camp refugee settlement area in the West Nile region in northern Uganda, with high psychological distress

What does the study involve?
Participating villages in the Rhino Camp refugee resettlement area are randomly allocated into two groups. Women in one group are invited to participate in five sessions of two hours of audio-recorded guided self-help, with a picture-book that illustrates the audio material. Women in the other group receive enhanced usual care, consisting of a community health care worker describing psychological distress, its causes, and what one can do to decrease psychological distress; and access to existing mental health services provided at primary care facilities. Various indicators of mental health are measured before, immediately after, and 3 months after completion of the intervention.

What are the possible benefits and risks of participating?
Likely benefits include reduced psychological distress and improved wellbeing. Discussion of difficult feelings may lead to temporary increases in psychological distress. In two small previous studies this risk has not been observed occurring.

Where is the study run from?
Peter C. Alderman Foundation (Uganda)

When is the study starting and how long is it expected to run for?
May 2016 to January 2018

Who is funding the study?
Enhancing Learning & Research for Humanitarian Assistance (ELRHA) Research for Health in Humanitarian Crises (R2HC)

Who is the main contact?
Dr Wietse Tol

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
SH+UG

Study information

Scientific Title
Guided self-help to reduce psychological distress in South Sudanese refugees in northern Uganda: a cluster randomized trial

Study objectives
A guided self-help intervention will lead to larger reductions in psychological distress than enhanced usual care.

Ethics approval required
Old ethics approval format

Ethics approval(s)

1. World Health Organization Ethics Review Committee, 12/07/2016, ref: RPC758
2. MildMay Uganda Research Ethics Committee, 04/10/2016, ref: #RECREF0307-2016

Study design
Cluster randomized trial

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Psychological distress

Interventions
Villages in the Rhino Camp refugee resettlement area are randomised to the following two conditions. Interviewers will be masked for study condition of villages.
1. The intervention condition will consist of a guided self-help intervention called Self-Help Plus (SH+). SH+ consists of five two-hour audio-recorded sessions, facilitated by a lay facilitator, as well as a picture book that illustrates the material from the audio sessions. The intervention comprises 2-hour sessions, weekly, for 5 weeks.
2. The control condition will consist of enhanced usual care, consisting of psycho-education by trained community health workers and access to mental health care services delivered in nearby health centers.
Various indicators of mental health are measured before, immediately after, and 3 months after completion of the intervention.

Intervention Type
Other

Primary outcome measure
Psychological distress, assessed using the Kessler 6 (K6) at pre-treatment (included as screening measure), immediately post-treatment, and 3 months after completion of treatment

Secondary outcome measures
Secondary outcomes:
1. Functional impairment, measured using the World Health Organization Disability Assessment Schedule 2.0, 12-item, interviewer administered version
2. Self-defined psychosocial goals, measured using PSYCLOPS
3. Depression symptoms, measured using the Patient Health Questionnaire 9 (PHQ-9)

4. Post-traumatic stress disorder symptoms, measured using the Posttraumatic Checklist 6 Civilian Version (PCL-C6)
5. Subjective wellbeing, measured using the World Health Organization Wellbeing 5 (WHO-5)

Mediator:
1. Psychological flexibility, measured using the Acceptance and Action Questionnaire 2 (AAQ-2)

Moderators:
1. Exposure to potentially traumatic events, measured using the Harvard Trauma Questionnaire (HTQ), part A
2. (Additional) health service use, measured using survey questions designed for this study

Other:
1. Economic indicators (for cost-benefit analyses), measured using survey questions designed for this study
2. Treatment contamination check, measured using survey questions designed for this study

All outcomes, mediators, moderators and the economic indicators are assessed at pre-treatment, immediately post-treatment, and 3 months after completion of treatment by a masked team of interviewers not involved in service delivery. To ensure masking, the contamination measure will be administered by intervention facilitators, between the immediate post-treatment follow-up and the 3-month follow-up.

Overall study start date
20/05/2016

Completion date
16/01/2018

Eligibility

Key inclusion criteria
1. Adults (18 years or older)
2. Women
3. Speaking Juba Arabic
4. Residing in the Rhino Camp refugee settlement area in the West Nile region in northern Uganda
5. Scoring above an established cut-off for psychological distress on the K6

Participant type(s)
Other

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
14 villages (7 in the intervention condition, 7 in enhanced usual care condition); screening in 2 groups of 20-25 participants in each village, for a total of 560-700 participants

Total final enrolment
694

Key exclusion criteria
1. Imminent risk of suicide
2. Observable signs of severe mental disorder

Date of first enrolment
20/03/2017

Date of final enrolment
13/04/2017

Locations

Countries of recruitment
Uganda

Study participating centre
Peter C. Alderman Foundation Uganda
Mawanda Road Plot#855
Kampala
Uganda
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Sponsor information

Organisation
World Health Organization

Sponsor details
Avenue Appia 20
Geneva
Switzerland
1211

Sponsor type
Other

Website
http://www.who.int/en/

Organisation
Peter C. Alderman Foundation

Sponsor details
261 Madison Avenue
9th Floor
New York, NY
United States of America
10016

Sponsor type
Other

Website
http://www.petercaldermanfoundation.org/

Organisation
World Health Organization

Sponsor details
-
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Switzerland
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Sponsor type
Government

Website
http://www.who.int/countries/che/en/

ROR
https://ror.org/01f80g185

Funder(s)

Funder type
Research organisation

Funder Name
Enhancing Learning & Research for Humanitarian Assistance (ELRHA) Research for Health in Humanitarian Crises (R2HC)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal

Intention to publish date
16/01/2019

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Mark van Ommeren, World Health Organization or Wietse Tol, Peter C. Alderman Foundation.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	13/08/2018	01/08/2019	Yes	No
Results article	results	01/02/2020	27/01/2020	Yes	No
Results article	secondary analysis	12/09/2023	14/09/2023	Yes	No