ISRCTN37820075 https://doi.org/10.1186/ISRCTN37820075

An efficacy study of sociotherapy group intervention in the Sexual Reproductive Health and Rights (SRHR) program in Burundi

Submission date
17/05/2016

Recruitment status
No longer recruiting

Registration date
27/05/2016

Overall study status
Completed

Last Edited
05/10/2016

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Sexual Reproductive Health and Rights (SRHR) is a concept of human rights which applies to sexuality and reproduction. These rights extend to equal opportunities, rights and conditions of all people to have a safe and satisfying sexual life, and to be able to decide over their own bodies without coercion, violence or discrimination. In communities in post-conflict areas, such as Burundi, SRHR-related problems are particularly common. A huge amount of young girls are not married legally and are deprived of their rights to adequate family planning, as well as being victims of domestic violence. This study is looking at a sociotherapy program (a type of talking therapy which focuses on the environment and relationships with others) which has been designed to improve negative SRHR related consequences. The aim of this study is to evaluate whether of a sociotherapy program within a comprehensive SRHR program is an effective way of improving negative SRHR related consequences.

Who can participate?
Those aged 16 and over with SRHR-related problems.

What does the study involve?
Participating collines (villages) in Burundi are randomly allocated to one of two groups. Those in the first group attend a course of 15 group sessions of the sociotherapy programe over eight weeks. The sessions are run by trained facilitators and involve group discussions, role playing, and learning techniques to boost self-awareness and mutual understanding. Those in the second group continue as usual for the duration of the study, and are offered the sociotherapy programe after the study has been completed. At the start of the study and then again after eight and 15 weeks, participants in both groups have their mental health, social wellbeing and social skills measured using a series of questionnaires.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
The study is run from Healthnet TPO Burundi and takes place in different collines (villiages) in 7 communes spread over three provinces: Bujumbura Rural, Bubanza and Cibitoke (Burundi)

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

Who is funding the study?
Dutch Embassy Burundi (Burundi)

Who is the main contact?
Professor Ivan Komproe

Contact information

Type(s)
Scientific

Contact name
Prof Ivan Komproe

Contact details
Healthnet TPO
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A Naturalistic Cluster Randomized Trial to study the efficacy of socio therapy group intervention in the SRHR program in Burundi

Study objectives
The aim of this study is to establish the efficacy of the group interventions sociotherapy on negative SRHR related consequences of participants among the target population of the project in three provinces in Burundi. Specification of the domains of negative SRHR related consequences are:
1. Psychosocial, family and community functioning,
2. Physical health, well-being and general mental health and
3). Psychological and social processes and rebuilding social structures of local communities.

The two main hypotheses are:
1. The group interventions sociotherapy is effective to reduce physical and mental health

complaints, distress and disability for SRHR related problems
2. The group interventions sociotherapy is effective to increase wellbeing and the individual and communal perspectives of (re)building social structures of communities

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Committee of the Lumière University in Bujumbura, 04/05/2016, ref: ULBU/Psy /03218/2016

Study design
Naturalistic cluster randomized trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
The negative consequences of violations of Sexual Reproductive Health and Rights (SRHR) on mental health, well-being and social functioning.

Interventions
The study will be conducted in different collines (villiages) in 7 communes spread over three provinces: Bujumbura Rural, Bubanza and Cibitoke. To avoid contamination of the intervention 15 collines (villiages) in these 7 communes are randomly allocated to the sociotherapy groups or control groups.

Intervention group: Participants attend a course of 15 group sessions of the Sociotherapy Intervention (ST) over a period of 8 weeks. These sessions are guided by trained facilitators and involve group discussions, role playing, practicing the Johari window, the square of autonomy and the four-circle model about culture in new environments technique, implementing insights about types of families, socialization, social systems, and social identity, listening and relaying the message, games and their importance, fundamental needs, emotions, the way to act in a new environment, communicating by signs (without words) and on prejudices.
These 15 sessions intervention consist of 6 phases with their own objectives to reach:
1. Security/peace
2. Confidence/trust
3. Mutual care and assistance
4. Mutual respect
5. New norms
6. Discussing the experienced change by reflecting the past and present situation.
All these objectives cover the following themes:
1. Having a desire/thirst to care for each other
2. Equality among the participants
3. Democracy during the sessions
4. Responsibility for the group process

5. Full participation
6. A focus on here, now and the future
7. Learning by doing to obtain and maintain change.

Control group: Participants are placed on a waiting list for the duration of the study. After the study they will be offered the opportunity to undergo the sociotherapeutic intervention.

Participants in both groups are followed up after 8 and 15 weeks

Intervention Type

Primary outcome(s)
1. Mental Health is measured using the five-item version of the Mental Health Inventory (MHI) at baseline, 8 and 15 weeks
2. Social Wellbeing is measured using the Subjective Wellbeing scale (SW-4) at baseline, 8 and 15 weeks
3. Social functioning is measured using the RAND SF-12 at baseline, 8 and 15 weeks

Key secondary outcome(s))
1. General Health complaints are measured using the SCL-90-R (items 1, 4, 12, 27, 42, 52, 56) at baseline, 8 and 15 weeks
2. Societal changes are measured at baseline, 8 and 15 weeks using:
2.1. The Sense of community index
2.2. The Sense of coherence scale (SOC-13)

Completion date
20/08/2016

Eligibility

Key inclusion criteria
1. Aged 16 years and older
2. Sexual Reproductive Health and Rights (SRHR) -related problems

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Sex
All

Key exclusion criteria
Those who require immediate medical treatment.

Date of first enrolment

25/03/2016

Date of final enrolment
29/07/2016

Locations

Countries of recruitment
Burundi

Study participating centre
Healthnet TPO Burundi
Avenue Muyinga N°21, Rohero I
Bujumbura
Burundi
BP 1110

Sponsor information

Organisation
Dutch Embassy Burundi

Funder(s)

Funder type
Government

Funder Name
Dutch Embassy Burundi

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes