Mental health, social functioning and social capital in Rwanda.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27457

Source
NTR

Brief title
N/A

Health condition

1. War;

2. mental health;

3. trauma related symptomology;

4. Rwanda;

5. group therapy;

6. social impact;

7. social networks;

8. alcohol abuse;

9. partner violence.

geestelijke gezondheid, sociaal functioneren, sociaal kapitaal, alcoholmisbruik, partner geweld

Sponsors and support

Primary sponsor: Academic Medical Centre Amsterdam
Source(s) of monetary or material Support: CORDAID

Intervention

Outcome measures

Primary outcome

Primary outcome measure is mental health, as measured by use of the Self Reporting Questionnaire 20 items (SRQ-20). This is a structured interview developed by the World Health Organization (WHO) as a screening tool for common mental disorders in primary health care settings, especially in developing countries. When patients are literate it can be self-administered, but in developing countries it is usually administered by lay interviewers. The instrument consists of 20 yes/no questions about mood, thinking capacity, feelings of anxiety and physical well-being. The SRQ-20 has been used in numerous settings, also as a screening instrument in community samples. Cut-off points vary considerably depending on setting (community, primary care, hospital) and culture. A cut-off point of 8 is widely used. During our pilot study we validated the instrument locally. We interviewed 99 respondents, who were also clinically assessed by clinicians who were blind for the SRQ-scores. We established a local cut-off score for caseness/non-caseness. The capacity of the SRQ-20 to identify probable
psychopathology in this setting proved to be sufficient. The AUC was 0.76. When analysed separately for men and women the SRQ-20 showed to perform equally well in men (AUC=0.74) and women (AUC=0.76). In evaluating the instrument as a potential screener for psychiatric disorder the most appropriate cut-off point is a trade-off between a high sensitivity and an acceptable specificity. From our analyses the optimal cut-off point for the SRQ-20 appeared to be 10/11 (sensitivity 0.69; specificity 0.79). However, when men and women were analysed separately the cut-off points differed. The optimal cut-off point for men is 8/9 (sensitivity 0.69; specificity 0.65), while the optimal cut-off point for women is 10/11 (sensitivity 0.81; specificity 0.80). Reliability is considered to be good: alpha=0.83 (men: alpha=0.81; women: alpha=0.85).

Secondary outcome

1. Social functioning, as measured by the Byumba Social Functioning Questionnaire (BSFQ). This instrument contains questions which have been derived from a list that resulted from previous research in Rwanda. The actual questions have been compiled and listed during focus group interviews with people living in Byumba. Questions concern common daily activities for women and men, respectively, such as dressing oneself or taking care of the children. Data from our pilot study revealed that the instrument’s reliability is sufficient to good: alpha=0.77 (men: alpha=0.77; women: alpha=0.73).

2. Social functioning will also be measured with the Medical Outcomes Study (MOS) Social

Functioning Scale 36 items (SF-36). This internationally widely used instrument is based on the WHO definition of health. Within this definition, health is divided into three domains: physical, mental, and social health. The SF-36 contains questions about functional impairment related to physical or psychological problems. In this study the instrument will be used to further found the validity of the BSFQ. For use in Rwanda, items of the SF-36 will be adapted if containing contextually inadequate phrases ('pushing a vacuum cleaner', 'walking blocks', 'playing golf'). Alternatives will be determined during discussions with local community members.

3. Social capital, as measured by use of the Social Capital Assessment Tool, short adapted version (SA-SCAT). This instrument contains questions used to get an impression of the respondents' connectedness to their social environment. They have been derived from a list of questions that resulted from previous research in various countries. The actual questions were compiled and listed during focus group discussions with people living in Byumba. This has resulted in a locally adapted version. Questions concern the way people feel connected to others in their living area, feel supported by others, get along and undertake common actions with others. Data from our pilot study revealed that the locally adapted version consists of five factors: Active Membership, Cognitive Social Capital, Individual Support, Group Support, and Participation. These factors are congruent with previous research and theory. Internal consistency of the factors ranges from 0.59 (Cognitive Social Capital) to 0.95 (Active Membership). In an effort to raise the instrument's psychometric qualities, a version will be used during this study with items added to its pilot study version, and yes/no answering options changed to Likert scales. Items to add will be determined during another round of discussions with local community members.

4. Alcohol use, as measured by use of the Alcohol Use Disorders Identification Test Consumption (AUDIT-C). This instrument contains 3 questions assessing the number and frequency of having 'drinks containing alcohol', a formulation which is suitable for use in a country where alcohol may often not be consumed in identifyable units like commercial bottles or standard glasses. The AUDIT-C has shown to be an effective screening instrument for alcohol misuse on primary care level. Subsequent validation in American clinical outpatients and in European samples, respectively, yielded different optimal screening thresholds. The instrument has not been validated locally during the pilot phase of this study. Therefore, after translation and back-translation, the instrument will only be used to explore change in alcohol use over time.

5. Partner violence, as measured by using elements of the Revised Conflict Tactics Scales, short form (CTS2S): the
'negotiation', 'psychological aggression', 'physical assault' and 'injury' scales. (The remaining scale concerns sexual coercion, a subject inacceptable to address in a short, one-time interview in Rwanda.) The CTS2 is the most widely used and men, respectively, such as dressing oneself or taking care of the children. Data from our pilot study revealed that the instrument's reliability is sufficient to good: alpha=0.77 (men: alpha=0.77; women: alpha=0.73). The CTS2 is the most widely used instrument for measuring family violence. The short form enables the CTS2 to be used when testing time is limited. There is only a clear indication so far that the validity of the CTS2S is comparable to the CTS2, and the CTS2S has not been validated locally during the pilot phase of this study. Therefore, the instrument will

be considered to only provide an indication of partner violence. The instrument classifies respondents into three severity levels: ‘none’, ‘minor only’ and ‘severe’, and creates mutuality types: ‘male partner only’, ‘female partner only’, and ‘both aggressive’. The latter is relevant as in this study only one of the partners of possible couples will be interviewed. As the 7-options-per-item answering system of the CTS2S is considered too complicated for the study population to provide valid answers, an adaptation to this will be designed and piloted after translation and back-translation.

Study description

Background summary

This study concerns a therapeutic group approach carried out in post-genocide Rwanda. Using a trauma perspective, the intervention method is specifically tailored to survivors of systematic violence. Next to
individual recovery it aims at the restoration of safety, mutual respect, trust, care, and the setting of democratic rules.
By use of a prospective controlled oncurrent groups design, the study measures the intervention’s effects on mental health, social functioning and social connectedness. Additionally, the study will seek to obtain data about changes in alcohol abuse and partner violence, as these arE frequent manifestations of posttraumatic psychopathology.

Study objective

The study aims to establish the effects of a therapeutic group intervention called sociotherapy, which is specifically tailored to traumatized survivors of systematic violence displaying a broad spectrum of affective and cognitive disturbances. It is hypothesized that mental health symptoms,
social functioning and social capital are positively impacted by the intervention, and that all three are interrrelated. It is also assumed that the intervention has a
positive influence on two specific manifestations of posttraumatic psychopathology: alcohol abuse and
partner violence.

Study design

As a baseline measurement the questionnaire will be taken at the start of the sociotherapy program (T0). Three months later (T1), directly after the sociotherapy groups have stopped meeting, all respondents will be taken an exit interview. As a follow-up, a third interview will be taken 6 to 8 months after the stop of the program (T2). In summary:

T0 = start of intervention

T1 = end of intervention, 3 months after T0
T2 = follow-up, 6-8 months after T1.

Intervention

The intervention is a therapeutic group approach, tailored to survivors of systematic violence. Verbal exchange, debate, exercises, games and practical support are key elements. Trauma symptoms are addressed through support, psychoeducation and advise. Main goals are the restoration of safety, mutual respect, trust, care, and the setting of democratic rules. Groups contain 10 participants. Meetings are weekly over a period of 3 months, and last 3 hours each. Group leaders are local people, familiar with the region's history and current living situation; they have received a 3 months' training from Equator staff and are regularly supervised.

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Eligibility criteria

Inclusion criteria

Inclusion criteria for sociotherapy groups:

1. Within a 6 years period all areas of Byumba province will be covered by the sociotherapy program. The sequence of areas is dictated by matters of actual convenience, and

determined by the program's local counterpart;

2. Group participants are aged 16 years or older;

3. The composition of groups is mixed (both sexes, various ethnic backgrounds, wide age distribution);

No strict criteria for participation in a sociotherapy group exist. There are two routes towards participation:

1. Sociotherapy group leaders, who are selected from persons generally regarded and accepted as leaders within their community, invite community members to participate on account of the seriousness of their psychosocial problems;

2. Community members themselves apply for participation because they think it will help solve their psychosocial problems, and group leaders subsequently include them.

Apart from emotional problems arising from the past confrontation with atrocities and losses during the war and genocide, community members currently experience a variety of problems such as poverty, bad housing, infectious diseases like HIV/AIDS, single parenthood, having to care for another family's children, having a spouse in detention, sudden arrests, bearing a curse from ancestors, neighbours or the family in law, etc.

No criteria have been defined to consider a person a problem case, the main reason being that it would automatically mean that people could also be excluded form group participation – a consequence lcoally considered as extremely undesirable. Another reason is formed by the still paranoid societal atmosphere in the region. People appear not to be willing to inform others about the nature of their problems or past traumatic experiences. They will only do so within the context of a sociotherapy group, after mutual confidence has been gained over a certain time. Therefore, it would be useless to ask detailed questions to possible future participants - it might even discourage participation. As a result, no criteria to enter a group have been defined, other than being considered or acknowledged a serious problem case by group leaders. Consequently, no case definition exists on the basis of which a control group can be composed.

There will be three study groups:

1. DE: participants of sociotherapy groups, directly exposed (DE) to the intervention;

2. IE: individuals living close to the group participants, indirectly exposed (IE) to the intervention;

3. NE: individuals that are not reached by the intervention program: the control group, or non-exposed (NE).

Ad 1 (DE): All participants (n=100) of 10 sociotherapy groups will be included in the DE group, without any further selection.

Ad 2 (IE): The IE study group (n=100) will be formed according to the following stepped procedure: 1) All respondents of the DE study group will be asked to list 5 people they live or work with and feel close to. These may be relatives they share the house with, neighbours they are daily in touch with, close friends they meet at least twice a week, or colleagues they closely collaborate with. 2) Then the collected lists will be blindly piled in a random order. 3)Then 1 person is selected from each list, by choosing the name of the 1st person from the first list, the 2nd from the second list, the 3rd from the third list, etc. After five subsequent lists, the 1st name of the sixth list will be selected, the 2nd of the seventh list, etc.

Ad 3 (NE): This control group (n=100) will be randomly selected in a region where no sociotherapy groups are, or have been, meeting, or will be meeting over the coming 9 months. A similar proportion of urban and rural areas as in the experimental (DE) group will be selected. A convenience sampling method will be used. Respondents will be randomly selected while at home or in their fields. An equal number of men and women per day will be interviewed. As no clear operational case definition can be formulated (see above), the matching of the experimental (DE) and the control (NE) group wil be done on the basis of another criterion: a similar mean SRQ score and sd at baseline as the intervention (DE) group, and an equal amount of men and women with the same age distribution as well.

Exclusion criteria

N/A

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-12-2007
Enrollment:	300
Type:	Anticipated

Ethics review

Positive opinion Date:	01-11-2007
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1087
NTR-old	NTR1120
Other	Academic Medical Center : RWST01
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A