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The Relaxation Exercise and Social Support Trial

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09/09/2010

Recruitment status
No longer recruiting

Registration date
10/09/2010

Overall study status
Completed

Last Edited
13/03/2013

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
082589

Study information

Scientific Title
The Relaxation Exercise and Social Support Trial: Does a community based psycho-social intervention (combined structured social support groups and progressive relaxing exercises) alter complaints from medically unexplained vaginal discharge among low-income married women, aged 18 - 49 years and residing in Hay el Sellom?

Acronym
RESST

Study objectives
Primary hypothesis:
The intervention will result in a change in medically unexplained vaginal discharge (MUVD) complaints compared with the control arm by 6 months.

Secondary hypotheses:
1. The change in MUVD complaints will be mediated by the positive influences of the intervention on CMD and somatisation
2. There will be commensurate improvements in secondary outcomes such as depressive and anxiety symptoms and somatisation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board at the Faculty of Medicine, American University of Beirut approved on the 29th January 2009 (ref: FHS.MK.03)

Study design
Community based single centre randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Medically unexplained vaginal discharge

Interventions
The intervention package will be given for six weeks. The package includes: combined trainer-supervised relaxation exercises (twice per week for 30 minutes/session) and group discussions (twice per week for 75 minutes/session). The trainer-supervised relaxation exercises consists of progressive muscle relaxation, guided imagery, stretching and breathing, and progressive resistance exercise. The women support group discussions consists of facilitated discussion on issues of concern to the women, incorporate problem solving techniques and social support. The relaxation exercises will be given twice a week for 30 minutes per session, over six weeks by trained physical fitness instructors, and the group discussion will also be given twice per week, for 75 minutes per session, over a six weeks period by clinical psychologists and assisted by co-moderates who were social workers. The fitness instructors will be trained prior to the intervention by an expert in muscle relaxation and guide imagery. The benefits to women enrolled in trial include, the provision of free childcare during sessions, free pelvic exam, and free laboratory tests.

No major risks are anticipated for the participating women in this trial. There will, however, be some discomforting issues, such as repeated pelvic exam and laboratory tests at baseline and at six months, an active commitment to attend sessions throughout the three-month intervention period, as well as answering some sensitive questions during the interview questionnaires. On

the other hand, as for the control group, they will be provided with a periodic mental health assessment during intervention delivery, free pelvic exam and laboratory tests at baseline and six months.

In particular, for the control (treat later group), two clinical psychologists will be in charge of monitoring them closely (every three weeks) by assessing their depression/suicidal status via administering the Arabic validated Hopkins Checklist-25 (depression subscale, which is comprised of 15 questions to measure depression coupled with an additional question on any plans to commit suicide during the past week). All women with a regressed depression status (whether in the intervention or treat-later group) or with plans to commit to suicide will be referred for free follow-up visits at community psychiatric clinic, which belongs to the Doctors' beyond Borders (Medicins Sans Frontier) and it is located in close proximity to Hey el Selloum, a neighbourhood called Burj el Barajneh.

The use of this psycho-social intervention as opposed to other more sophisticated psychological based methods (cognitive behavioural therapy [CBT] or interpersonal therapy [IPT]) was equally motivated by the fact that it requires less training and is more culturally acceptable, in a conservative-economically disadvantaged Muslim community. Other methods would require a larger number of well-trained experts as well as longer training periods before actual implementation, which is beyond the capacities of the trial community. The overarching aim of this trial was to adopt a simple low cost community-based approach (relying on moderate levels of education and experience), with the hope to be later taken over (if proved effective) by the local community centres. It should be noted that the different intervention components were pilot-tested before actual implementation.

The semi-structured support (SSS) sessions were designed to be partially directed, with semi-structured components. They also incorporate trainings on problem solving and social support. The aim behind this combination is to enable women to participate in the discussion as well as to build rapport. The main desired outcomes of the SSS components were: empathy, venting and problem solving.

The relaxation exercise component of the intervention aims to train the women how to engage in guided imagery exercises on their own at home. It is less likely that having the women to replicate some of the physical fitness package at home to result in contamination; even though intervention group women could have well informed the women in the control group about the package - they are less likely expected to actually engage them in exercising it). Besides, the relaxation exercise sessions are progressive in nature, i.e. did not follow the same routine-starting at 15 minutes and building up resistance to reach 30 minutes.

Each new session of the relaxation exercise package is designed to wrap up the techniques conducted in the previous sessions, touch upon at what is being practiced at home and proceed by adding an additional new technique. The sessions reach a total of 30 minutes.

Attendance will be continuously monitored at the beginning of each session (SSS and relaxation exercise). A checklist will also be used to indicate the techniques learnt in sessions, techniques practised at home, etc.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Reported MUVD at six months (which is also assessed at six weeks upon the completion of the intervention for the intervention group). A woman is considered to have MUVD, if she reported a complaint of vaginal discharge as assessed by the question: "are you complaining currently from vaginal discharge?" and is concurrently not suffering from any RTIs, as confirmed by pelvic exam and laboratory tests (using swabs). Further questions will also be asked of the women to note whether or not they are bothered by MUVD, as well as to indicate the colour, odour, thickness, consistency and frequency. Besides, relevant health service use such as consultations for MUVD and associated treatments will also be explored.

Key secondary outcome(s))
1. Common mental disorder (CMD): the Hopkins Symptom Checklist 25 (HSCL-25) (individual scores on anxiety ranging between 2.0 - 3.2 and/or depression ranging between 2.1 - 3.3 are considered symptomatic) will be used to assess common mental disorders.
2. Somatisation: will be assessed using The Scale for Assessment of Somatic Symptoms (SASS)

Other measures/cofactors included:
3. Socio-demographic factors: age, education, employment status, family composition (presence of extended family members), number of children present (by age of each child), housing tenure (owned or rental), number of rooms, and household income
4. Women's reproductive and obstetric history (e.g. pregnancies, live births, abortions, still births)
5. Social support: will be assessed using questions from the Urban Health Survey, already translated into Arabic

Timing of outcome assessment:
The outcomes relating to CMDs will be assessed at screening, 1.5 and six months after randomisation, and somatisation were assessed at baseline and six months. The laboratory tests which will be conducted to rule out RTIs were assessed at baseline and at six months. The socio-demographic characteristics and reproductive history of the women will be assessed only at baseline, while, social support factors will be assessed at both baseline and at six months.

Completion date
18/11/2009

Eligibility

Key inclusion criteria
1. Currently married women, 18 - 49 years of age
2. Women who report of symptoms of MUVD
3. Women who score low to moderate levels of common mental disorders (CMDs), based on the study screening tool for common mental disorders (Hopkins Checklist 25)
4. Women who are willing to take part in the study by signing an informed consent after explaining the study process
5. Women who upon screening have none of the exclusion criteria listed below

Participant type(s)
Patient

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Pregnancy
2. Menopause. Menopausal women are excluded (definition of menopause: at least one year since last menses) because:
2.1. Frequency of MUVD among older is much lower
2.2. Young women in the reproductive age share different concerns than older women
2.3. The physical activity component of the intervention may not be suitable for older women
2.4. Older women suffer from a distinct set of physiological symptoms when compared to women in the reproductive age group like hypersomnia, hot flashes, and so on. Also, menopausal women suffer from explained vaginal discharge due to vaginal dryness.
3. Less than 8 weeks postpartum
4. Hysterectomy. Women with hysterectomy are excluded because they could be predisposed to some types of infections as a result of the removal of the uterus.
5. Women who score very low or severe levels of CMDs
6. Women who report having been treated for severe mental illness such as bi-polar depression, and schizophrenia

Date of first enrolment
30/03/2009

Date of final enrolment
18/11/2009

Locations

Countries of recruitment
Lebanon

Study participating centre
Riad el Solh 1107-2020
Beirut
Lebanon
11-02-36

Sponsor information

Organisation
American University of Beirut (Lebanon)

ROR
https://ror.org/04pznsd21

Funder(s)

Funder type
Charity

Funder Name
The Wellcome Trust (UK) (grant ref: 082589)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	09/11/2012		Yes	No
Protocol article	protocol	25/08/2011		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes