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Energy in Balance: an intervention aimed at migrant women with medically unexplained symptoms

Submission date
18/05/2018

Recruitment status
No longer recruiting

Registration date
10/07/2018

Overall study status
Completed

Last Edited
09/04/2021

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Medically unexplained symptoms (MUS) are quite common in general practice. Referral to medical specialists does not reveal an organic cause and patients are referred back to their general practitioner. This results in frequent consultations without symptom reduction. These patients are costly not only because of direct medical costs, but also because of indirect costs resulting from sick leave and presenteeism. Existing approaches are not self-evident for migrant and low educated patients. Therefore, an alternative intervention has been developed in the Netherlands designed for female migrant patients who frequently visit their general practitioner and experience low levels of energy. The intervention aims to create opportunities to achieve positive experiences in different domains of life. Its purpose is to increase self-esteem and self-confidence which are necessary for empowerment, energy increase and quality of life. The aim of this study is to determine the cost-effectiveness of this new intervention as compared to care as usual.

Who can participate?
Female migrant patients, aged between 26 and 64, who had a contact with the participating general practices in this study

What does the study involve?
Participating general practices are randomly allocated to two groups, the intervention group and the control group. The intervention comprises a series of 13 group meetings including an introductory meeting, eight meetings that focus on specific themes, two visits to community centers or organizations, one concluding session and an evaluation meeting. The actual content of the group meetings is adapted to the specific group composition. The intervention takes place in groups because groups may contribute to the treatment goals: participants may stimulate and help each other, and it may help to increase their social network. Before the group meetings, an individual intake aims at defining the individual goals of each participating person. The intervention group meetings are guided by either a psychologist, a social worker or a socio-psychiatric nurse. Training for the intervention group has been provided shortly before the actual launch of the intervention by a coach, who was also involved in the development of the

intervention. In the control group participants receive care as usual as provided by their GP. Patients' quality of life and the costs (medical and non-medical) are measured 14 months later.

What are the possible benefits and risks of participating?
Possible benefits include better quality of life, higher energy level, higher self-esteem, more social contacts/support, less health complaints, and lower frequency of GP visits. No risks are expected.

Where is the study run from?
1. Erasmus School of Health Policy and Management (Netherlands)
2. Artsengroep Persoonsstraat (Netherlands)
3. M.C. Verbeek-Poot, huisarts (Netherlands)
4. Huisartspraktijk Jansen (Netherlands)
5. Gezondheidscentrum Nieuwe Westen (Netherlands)
6. Praktijk Mozaiek (Netherlands)
7. Gezondheidscentrum Tarwezigt (Netherlands)
8. Huisartspraktijk Nusteling (voorheen Harmsen en Lo Fo Wong) (Netherlands)
9. Huisartspraktijk Bijl (Netherlands)
10. Gezondheidscentrum Beverwaard (Netherlands)
11. Gezondheidscentrum Randweg (Netherlands)
12. Gezondheidscentrum Sint-Mariastraat (Netherlands)

When is the study starting and how long is it expected to run for?
January 2012 to July 2014

Who is funding the study?
ZonMw (Netherlands)

Who is the main contact?
Dr Anushka Choté
chote@eshpm.eur.nl

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
NL40069.078.12

Study information

Scientific Title
Energy in Balance: the cost effectiveness of an intervention aimed at migrant women with medically unexplained symptoms

Acronym
EiB

Study objectives
EIB intervention is more cost effective than care-as-usual.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medisch Ethische Toetsingscommissie Erasmus MC (Medical Ethics Board Erasmus MC), 11/12/2012, ref: MEC-2012-418

Study design
Cluster randomised controlled trial in general practice

Primary study design
Interventional

Secondary study design
Cluster randomised trial

Study setting(s)
GP practice

Study type(s)
Quality of life

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
Medically unexplained symptoms in general practice

Interventions
The study has been conducted in Rotterdam, the second largest city of the Netherlands. In Rotterdam 37,4% of the population has a non-western background. The study has been carried out in general practices willing to participate in the study and willing to give permission to make use of their patient information system for selection of patients. The study has been setup as a cluster randomized trial with two arms. Participating general practices were the clusters that were randomly allocated to two arms, the intervention group and the control group. Cluster randomization was chosen because the intervention was partly community oriented, which made it necessary that participants belonging to the same intervention group were living in the same neighborhood.

The intervention comprises a series of 13 group meetings including an introductory meeting, 8 meetings that focus on specific themes, two visits to community centers or organizations, one concluding session and an evaluation meeting. The actual content of the group meetings is adapted to the specific group composition. The intervention takes place in groups because groups may contribute to the treatment goals: participants may stimulate and help each other, and it may help to increase their social network. Prior to the group meetings, an individual intake aims at defining the individual goals of each participating person. The intervention group meetings are guided by either a psychologist, a social worker or a socio-psychiatric nurse. Training for the intervention group has been provided shortly before the actual launch of the intervention by a coach, who was also involved in the development of the intervention.

In the control condition participants received care as usual as provided by their GP

Intervention Type
Behavioural

Primary outcome measure
1. Quality of life measured by SF-12 at baseline and follow-up (14 months later)
2. Costs (medical and non-medical) measured at baseline and follow-up

Secondary outcome measures
1. Depressive symptoms, assessed using the Patient Health Questionnaire-9 (PHQ-9). It assesses the presence of depressive symptoms in the past two weeks with four response options (‘not at all’, ‘several days’, ‘more than half the days’, ‘nearly every day’) and is often used in primary care settings The PHQ-9 score ranges from 0 to 27, because each of the 9 items can be scored from 0 (‘not at all’) to 3 (‘nearly every day’) . The PHQ-9 is part of the full PHQ for assessment of mental disorders.
2. Somatic symptoms, assessed using the Patient Health Questionnaire-15. The PHQ-15 is a validated instrument for detecting somatization disorders. The PHQ-15 comprises 15 somatic symptoms derived from the full PHQ. In this study 13 of the PHQ-15 somatic symptoms are included in the somatic symptom subscale. In this subscale patients are asked to rate the severity of each symptom as ‘not bothered at all’, ‘bothered a little’ or ‘bothered a lot’. Thus, in determining the score, each individual symptom is coded as 0, 1 or 2 and the total score ranges from 0 to 26. For Turkish speaking participants we made use of an existing Turkish translation of the PHQ.
2. Loneliness, measured using the De Jong Gierveld Loneliness Scale, a validated and reliable instrument for measurement of overall, emotional and social loneliness. The 6-item scale was

used in which the patients are asked to what extent the statements apply to them. The scale consists of 6 statements on a 3-points scale (yes, more or less and no). Scale scores range from 0 to 6. Higher scores indicate higher loneliness.
3. Self-esteem, measured using the Rosenberg Self-Esteem Scale, a 10-item scale in which patients are asked to rate their agreement with 5 positively and 5 negatively worded self-statements on a 4-points scale ranging from 'strongly agree' to 'strongly disagree' The total score (that ranges from 0 to 30) is calculated such that higher scores reflect higher self-esteem.
Measured at face-to-face interviews at baseline (T0) and 14 months (T1) after inclusion

Overall study start date
01/01/2012

Completion date
01/07/2014

Eligibility

Key inclusion criteria
1. All female patients, aged between 26 and 64 years of age that had a contact with the general practice participating in this study in the year before a reference day, depending on the date a GP was included
2. Having at least 6 contacts in the year preceding the study
3. Having been diagnosed by the GP by means of preferable 4 or more ICPC codes below 30 in the last 60 or 12 months
This inclusion process was performed by the researchers, based on the information obtained from the Health Information System (HIS) of the participating practices.
4. Having a migrant background
Since the HIS does not include this information, this part of the inclusion process was carried out by the participating GPs

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
N=180; 20 clusters with 9 participants each

Key exclusion criteria
1. Patients not able to communicate in Dutch
2. Patients in treatment at a mental health or social welfare service. Again, the HIS does not include this information, therefore this part of the selection process was carried out by the participating GPs
3. All those suffering at any point in time from:
3.1. Serous psychopathology
3.2. Multiple sclerosis, Parkinson's disease and epilepsy

3.3. Down syndrome, HIV/Aids, blindness and liver cirrhosis
4. All those who suffered in the year in which they also had 6 contacts or more with their GP:
4.1. Acute alcohol abuse, drug and medication abuse, memory and concentration disorders
4.2. Unwanted pregnancy, abortus provocatus, delivery of a death child
4.3. Anorexia, boulimia
4.4. Problems as a consequence of violence
4.5. Any form of cancer
This part of the exclusion process again was performed by the researchers, based on the information obtained from the Health Information System of the participating practices.
5. Patients suffering from the following chronic diseases, because frequent consultations may be associated with such diseases:
5.1. Diabetes
5.2. Hypertension
5.3. Cardiovascular disease
5.4. Asthma
5.5. COPD
5.6. Anxiety
5.7. Depression

Date of first enrolment
15/01/2013

Date of final enrolment
27/07/2013

Locations

Countries of recruitment
Netherlands

Study participating centre
Erasmus School of Health Policy and Management
Burg. Oudlaan 50
Rotterdam
Netherlands
3062 PA

Study participating centre
Artsengroep Persoonsstraat
Netherlands
3071 EK

Study participating centre

M.C. Verbeek-Poot, huisarts
Netherlands
3078 XS

Study participating centre
Huisartspraktijk Jansen
Netherlands
3071 JP

Study participating centre
Gezondheidscentrum Nieuwe Westen
Netherlands
3022 SG

Study participating centre
Praktijk Mozaiek
Netherlands
3074 LB

Study participating centre
Gezondheidscentrum Tarwezigt
Netherlands
3081 CN

Study participating centre
Huisartspraktijk Nusteling (voorheen Harmsen en Lo Fo Wong)
Netherlands
3082 KC

Study participating centre
Huisartspraktijk Bijl
Netherlands
3076 KV

Study participating centre

Gezondheidscentrum Beverwaard
Netherlands
3077 JS

Study participating centre
Gezondheidscentrum Randweg
Netherlands
3074 BJ

Study participating centre
Gezondheidscentrum Sint-Mariastraat
Netherlands
3014 SH

Sponsor information

Organisation
Erasmus School of Health Policy and Management

Sponsor details
Burg. Oudlaan 50
Rotterdam
Netherlands
3062 PA

Sponsor type
University/education

ROR
https://ror.org/057w15z03

Funder(s)

Funder type
Research organisation

Funder Name
ZonMw

Alternative Name(s)

Netherlands Organisation for Health Research and Development

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Netherlands

Results and Publications

Publication and dissemination plan
Study protocol (including analysis plan) is available (in Dutch only) by contacting Dr Choté.

Plans for publications (in peer reviewed journals):
1. Study design (intended publication date: end of 2018)
2. Results of cost-effectiveness study (intended publication date: end of 2018/early 2019)

Intention to publish date
31/12/2018

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Anushka Choté (chote@eshpm.eur.nl). Data: baseline (T0) and follow up (T1) data at patient level, based on primary and secondary outcome measures and demographic characteristics. As no explicit consent from participants was obtained for sharing the data, data can be made available only in close collaboration and under supervision of project leader (or representative). Data dictionaries are available upon request. Applicants should specify which data are necessary for their intended analyses. From this dedicated data sets will be constructed.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	cost-effectiveness results	05/10/2015		No	No