

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

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|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>18/05/2018   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>10/07/2018 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>09/04/2021       | <b>Condition category</b><br>Signs and Symptoms   | <input type="checkbox"/> 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 Tarwezig (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

Prof Anna Petra Nieboer

### ORCID ID

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### Contact details

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3062 PA  
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# Additional identifiers

## Protocol serial number

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

## Primary study design

Interventional

## Study design

Cluster randomised controlled trial in general practice

## Study type(s)

Quality of life

## 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(s)**

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

## **Key secondary outcome(s)**

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

## **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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **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 Tarwezig**  
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

**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****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](mailto: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? |
|----------------------------------|----------------------------|--------------|------------|----------------|-----------------|
| <a href="#">Abstract results</a> | cost-effectiveness results | 05/10/2015   |            | No             | No              |

