

# Development of a training program for immigrant women: a practical intervention based on physiotherapy

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<b>Registration date</b> 24/04/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 01/09/2021	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Women from ethnic backgrounds are increasingly experiencing mental and physical health problems and social vulnerability is common among this group. While Denmark is facing growing inequality between Danish women and immigrant women in relation to exercise and health, research on interventions and targeted exercise programs for immigrant women is generally limited. This study aims to test the feasibility of a physiotherapeutic supervised exercise program developed to increase health benefits, physical and psychological wellbeing, and increase motivation to live a healthier lifestyle. One of the most important aspects of the study is involving the women in the development of the program. Further, the study aims to allow its findings to serve as a guide for other physiotherapists who work with minority groups to allow them to implement supervised programs to recruit and maintain immigrant women in physical exercise programs.

### Who can participate?

Women with an ethnic background other than Danish who have migrated from their country of origin and now reside in Denmark. The minimum age is 30 years, because according to the office of Employment and Social Administration, the age of 30 accounts for 25% of the unemployed population in one of the biggest municipalities in Denmark. Women are included if they are considered to benefit most from increased physical movement in their everyday lives. This includes women with mental and physical illnesses (e.g. type 2 diabetes and musculoskeletal problems)

### What does the study involve?

The study involves a 12-week exercise program. The physical exercises employed in the training sessions consisted of a mixture of endurance, strength, coordination, balance, and resistance training, often including exercises for specific body parts requested by the women. The prioritization of these training types is based on the wishes of the participants. Exercises for weight loss, flat bellies, and reduced pain levels have the highest priority. The exercise intensity is adjusted to the women's overall training condition. The participants' physical condition is measured at the start of the study and after the 12-week exercise program

What are the possible benefits and risks of participating?

The benefits of participating in the exercise program include increased knowledge about a healthier lifestyle and exercising in daily living, pain reduction, and increased energy and general mental and physical wellbeing. Furthermore, the social aspect of exercising together with other women is important, where they can help and support each other.

Where is the study run from?

The study is run from Odense, Denmark

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

September 2017 to September 2018

Who is funding the study?

This project was fully funded by the Association of Danish Physiotherapists (Praksisfonden fra Danske fysioterapeuter). The funders had no role in the design of the study, conduct, analysis and interpretation of the data or in writing the manuscript.

Who is the main contact?

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## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

J.nr. 29 2017-41-5197

# Study information

## Scientific Title

Development of a supervised exercise program for immigrant women: feasibility study of a practical intervention in a physiotherapy setting

## Study objectives

It is feasible to conduct and to maintain an exercising program for immigrant women.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

The study does not require any ethics approval regarding to jf. § 14, stk. 1, as the study does not contain or give any biological data to third persons. The study has been approved/defined as not requiring ethics approval by the Ethics Committee of Southern Denmark (De videnskabetiske komitéer, Region Syddanmark, Damhaven 12, 7100 Vejle, Denmark; Tel: +45 (0)76631000; Email: komite@regionsyddanmark.dk), 10/07/2017, ref: S-20172000-115

## Study design

Interventional feasibility study

## Primary study design

Interventional

## Secondary study design

Non randomised study

## Study setting(s)

Community

## Study type(s)

Quality of life

## Participant information sheet

Not available in web format, please use contact details to request a participant information sheet. The participant information sheet is written in Danish language.

## Health condition(s) or problem(s) studied

Immigrant women aged >30 years who are inactive with several diseases such as type 2 diabetes and/or heart disease or pain symptoms as well as mental difficulties

## Interventions

After the completion of baseline focus-group interviews, physical-strength tests, and a patient questionnaire, there was a 12-week supervised training period based on principles from physiotherapy.

The physical exercises employed in the training sessions consisted of a mixture of endurance, strength, coordination, balance, and resistance training, often including exercises for specific body parts requested by the women. The prioritization of these training types was based on the

wishes of the participants. Exercises for weight loss, flat bellies, and reduced pain levels had the highest priority. The program contained elements of individual training (for example exercises for the neck after a woman had to cook for many hours the night before training), and the exercise intensity was adjusted to the women's overall training condition. Most women had no or little experience in physical training, and therefore the training was usually low-level intensity with many repetitions. The sessions did not include a great deal of theoretical education, partly based on the information attained from the women in the interviews as they didn't want to have a lot of theory, but also because of the generally low level of Danish language skills. However, individual explanations and guidance were used to optimize each woman's personal gain from the training.

The training was followed up by reinterviewing and retesting the participating women. Prior to and after the exercise program the researchers conducted focus group interviews as well as the Eq5d questionnaire (anonymous) to collect data about the participants. The focus group interviews were based on questions, thoughts and wishes about the exercise, the content and their expectations. The women were included during the whole process of conducting the exercise program. Furthermore, their physical health was tested, as they did the sit-to-stand-test as well as 6-meters walking test and their weight and fat percentage were measured.

To describe the women's physical results after completion of the 12 weeks of exercise, the researchers compared the results of the physical test at baseline with the retest data using mean differences and t-tests for parametric data, and the Wilcoxon signed-rank test for the nonparametric data. They used the qualitative data from the focus group interviews for planning the intervention of the study. Further, they analyzed data of the women's experience with and attitude towards the program, and their satisfaction after completion. They used data from all the participating women in the evaluation at the end of the exercising program. The analysis contained themes of interest as logistics/execution of the sessions, the content of the program and expectations. These themes were supplemented by an observational analysis of the women's participation in the program. Interviews were recorded on smartphones and transcribed. Two independent authors read the transcripts and found quotations to support the themes. The researchers used the quantitative data from the participants' questionnaires for descriptive analysis, presented as numbers or means with 95% confidence intervals. Registration data described participation and withdrawal rates were presented as percentages.

## **Intervention Type**

Behavioural

## **Primary outcome measure**

1. Physical condition (mainly endurance) is measured using the 6-minute walk test (6MWT) at baseline and after the 12-week exercise program
2. Physical condition (mainly physical function of the knees) is measured using the sit-to-stand (STS) test at baseline and after the 12-week exercise program
3. Mental health (including self-rated health) is measured using the EQ5D questionnaire at baseline and after the 12-week exercise program
4. Participants' expectations and wishes are measured using focus group interviews at baseline, with the themes: logistics/execution of the sessions; content of the program; expectations
5. Participants' qualitative statements collected using focus groups interviews with the themes: pain reduction, general wellbeing, motivation and awareness after completing the 12-week exercise program
6. BMI and fat percentage measured using weight at baseline and after 12 weeks of the exercise program

**Secondary outcome measures**

1. Participants' feedback and thoughts regarding the exercise program measured using a verbal evaluation in the middle of the exercise program (after 6 weeks) and after completing the 12-week exercise program
2. Participants' motivation toward the exercise program measured with verbal evaluation at 6 and 12 weeks
3. Participants' attendance in the exercise program measured using a registration system during the exercise program

**Overall study start date**

01/09/2017

**Completion date**

01/09/2018

**Eligibility****Key inclusion criteria**

1. Women with an ethnic background other than Danish, who have migrated from their country of origin and now reside in Denmark
2. Minimum age 30 years
3. Women who would benefit most from increased physical movement in their everyday lives, including women with mental and physical illnesses (e.g. type 2 diabetes and musculoskeletal problems)

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

19

**Total final enrolment**

29

**Key exclusion criteria**

1. <30 years old
2. Males
3. No immigrant background
4. Exercise experience

**Date of first enrolment**

02/01/2018

**Date of final enrolment**

02/04/2018

## Locations

### Countries of recruitment

Denmark

### Study participating centre

#### Fysio Danmark Odense

Vestre stationsvej 11

Odense

Denmark

5000

### Study participating centre

#### BoligSocialtHus korslækkeparken

Nyborgvej 287

Odense

Denmark

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## Sponsor information

### Organisation

Danske fysioterapeuter

### Sponsor details

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### Sponsor type

Research organisation

### Website

fysio.dk

### ROR

<https://ror.org/03aewyp97>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded: Praxisfonden Danske Fysioterapeuter: Danish physical therapists funding

# Results and Publications

## Publication and dissemination plan

The researchers intend to publish as soon as possible in the journal BMC Women's Health.

## Intention to publish date

01/09/2019

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Lars Morsø (lars.morsoe@rsyd.dk).

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		07/07/2021	01/09/2021	Yes	No