

KWIEK. A randomised controlled trial investigating the effectiveness of an integrated multidimensional lifestyle program on disability, self-management and quality of life in frail older adults aged 65 and over living independently in the rural community of Wijk bij Duurstede and Maarn-Maarsbergen (community of Utrechtse Heuvelrug).

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39577

Source

ToetsingOnline

Brief title

KWIEK, a lifestyle program, testing its effectiveness in frail elderly

Condition

- Other condition

Synonym

selfmanagement; frail older adults

Health condition

bewegen, eenzaamheid, voedingspatroon en polyfarmacie (fysiotherapie en psycho-sociaal)

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Ministerie van OC&W, Gemeente Wijk bij Duurstede en Fysiotherapiepraktijk Weusthof (eigen bijdrage)

Intervention

Keyword: disability, frail older adults, life style program, multi-dimensional

Outcome measures

Primary outcome

Primary outcome of the study is disability (measured by Groningen Activity Restriction Scale (GARS)).

Secondary outcome

Quality of Life measured by means of The Short Form-12 (SF-12) and self-management in daily living by means of the KATZ-ADL (6) and the Self Management Ability Scale (SMAS-30).

Study description

Background summary

Frailty is a dynamic state affecting an individual who experiences losses in one or more domains of human functioning (physical, psychological or social), which is caused by the influence of a range of variables and which increases the risk of adverse outcomes, leading to the endpoint of frailty: functional disability. Frailty is assumed to be reversible and malleable by specific interventions that focus on risk factors. Knowledge about frailty offers care professionals at individual patient level a good opportunity for estimating future health risks and vulnerability in functionality of daily activities, social participation and self-management. Organizing demand-driven care tailor-made interventions with an important role for primary care, screening of frail groups and multidisciplinary cooperation are needed.

Study objective

In the proposed study we aim to investigate determinants of frailty and the effectiveness of a structured multi-dimensional intervention program called **KWIEK** on frailty, self-care/functional abilities and quality of life, in different subgroups of frail older adults. Next to this we will investigate the effect of the separate components of the KWIEK program on medication-use, physical fitness, mental health and nutritional status? Finally, the effect of **KWIEK** on primary care consumption will be evaluated.

Study design

A longitudinal cohort study will be started to describe prevalence and incidence of frailty. Within this cohort a nested randomized controlled trial will be started to answer the research questions on the effectiveness of the KWIEK Program on the course and level of frailty and in preventing the onset of frailty.

Intervention

KWIEK is a group-based program. Mean group size is 8 - 10 older adults. The KWIEK-program consist of four components: monitoring medication by means of Prescribing Optimization Method, a physical trainings program, an assertiveness program to develop social skills, a nutritional education programme.

Study burden and risks

The risks associated with participation are minimized. The training of daily activities are adapted to the target group. Other interventions concern welfare or information and prevention and our estimates are free of risks. Baseline measurement, measurement in between and follow up will take one hour. The length of of KWIEK-program is nearly 22 weeks (including holidays).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Groninger Frailty Index (GFI) score of 1 or higher

Living on their own/community of Wijk bij Duurstede

Age 65 and over; This study focuses on community-dwelling older people (≥ 65 years) in different stages of our frailty concept. 400 older adults are included, of whom 200 will receive the intervention, 200 will be included in the control condition. ; The GFI is a screener for frailty. Frailty is indicated at a score from 3 or higher. In this study older adults with different stages of frailty are included, which enables us to investigate the effectiveness of the intervention in these different stages of frailty.

Exclusion criteria

Cognitive impairment (MMSE < 23)
Severy immobility as wheelchair dependent
Inability to communicate in Dutch

Study design

Design

Study type: Interventional
Intervention model: Parallel
Allocation: Randomized controlled trial
Masking: Single blinded (masking used)

Primary purpose: Prevention

Recruitment

NL
Recruitment status: Recruitment stopped
Start date (anticipated): 31-08-2012
Enrollment: 400
Type: Actual

Ethics review

Approved WMO
Date: 30-08-2012
Application type: First submission
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO
Date: 27-02-2014
Application type: Amendment
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL37516.041.12