

# KWIEK. Investigating the effectiveness on self-management and quality of life of an integrated multidimensional lifestyle program in older adults.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Recruiting
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON23460

### Source

NTR

### Brief title

KWIEK

### Health condition

frailty  
disabled  
multidimensional  
lifestyle program  
self-management

## Sponsors and support

**Primary sponsor:** UMC Utrecht,  
division Julius Centrum  
Department of General Practice

**Source(s) of monetary or material Support:** ZonMw, Municipality Wijk bij Duurstede, projectpartners.

## Intervention

## Outcome measures

### Primary outcome

Primary endpoint for the effectiveness of the KWIEK intervention-part is the change in disability or limitations in daily living (GARS).

### Secondary outcome

1. Change in functional status (KATZ);
2. Change in quality of life (SF-12);
3. Change in self management abilities (SMAS-30);
4. Health care consumption (additional questions; see Attachment F1.2);
5. Optimization of medication (POM);
6. Change in physical fitness (grip strength, 6 MWT, TUG, Demmi);
7. Change in mental health (HADS, de Jong-Gierveld Loneliness Scale);
8. Change in nutritional status (SNAQ65+, MUAC).

## Study description

### Background summary

Rationale:

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.

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: In November 2011 a longitudinal cohort study in the community of Wijk bij Duurstede started to describe prevalence and incidence of frailty. Within this cohort a nested randomized controlled trial will be started (May 2012) 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.

Study population:

Older adults (65 years or older) living independently in the community of Wijk bij Duurstede. Within this cohort study (n = 1066) a group of in total 400 older adults (score of 1 or higher on the GFI) will be recruited for the nested randomised controlled trial. Criteria for exclusion: Cognitively impaired (MMSE < 23 (0-30); Severe immobility or a language barrier.

Intervention:

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

Main study parameters/endpoints:

Primary outcome of the study is disability (measured by Groningen Activity Restriction Scale (GARS). Secondary outcome measures are Quality of Life measured by means the Short-Form 12 (SF-12) and self-management in daily living by means of the KATZ-ADL and the Self Management Ability Scale (SMAS-30).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks associated with participation are minimized. The physical training program of daily activities is adapted to the target group. Other interventions concern welfare or information

and prevention and our estimates are free of risks. Baseline measurement, measurements in between and follow up will take one hour. The length of the KWIEK-program is nearly 22 weeks (including holidays).

## **Study objective**

We will investigate the effect of the separate components of the KWIEK program on medication-use, physical fitness, mental health and nutritional status in a group frail, living independently, older adults (65 years or older).

Finally, the effect of KWIEK on primary care consumption will be evaluated.

## **Study design**

Every 20 weeks a new group of 10 participants starts the lifestyle program.

Every year (2011- 2013) in november, by means of a cohortstudy, the control group is assessed.

## **Intervention**

The KWIEK-intervention is a structured and integrated intervention program that consists of the following four components:

1. Medication improvement;
2. Improving physical fitness;
3. Improving social skills;
4. Improving nourishment.

Component 1) for medication improvement the POM-method (Prescribing Optimization Method) will be used.

Component 2) of the program focuses on physical fitness and aims to improve muscle strength, walking speed, fatigue through exercise. In this program daily activities which are considered the most problematic by the individual are trained. Walking stairs, shopping,

moving outdoors, up from a chair or a bed etc. During these exercises the interplay of cognitive, perceptual, and motor functions and its closely linking to the individual's dynamic environment is trained.

Component 3) Social skills; especially for KWIEK an assertively training was developed. The main focus of this training is improving self-confidence and self-management enhancement; ask for support and sharing thoughts, saying no, making plans for the future. In this training the ACTOR-method is used [29]. In this method an exercise program and social skills program are integrated.

Component 4) Improving the nutritional status; a nutrition education program is offered. The aim of this intervention is to increase the awareness about healthy diet and to increase self-care in nourishment. The final goal of this education program is to promote and maintain a healthy nutritional status and to optimize weight.

The control group is a wait list control group. After completion of the intervention period, the control group members have the priority to start with the KWIEK program.

## Contacts

### **Public**

UMC Utrecht,  
division Julius Centrum<br>  
Department of General Practice<br>  
Huispost Str. 6.131<br>  
PO Box 85500  
Bas Steunenberg  
Utrecht 3508 GA  
The Netherlands  
+31 (0)88 7555098

### **Scientific**

UMC Utrecht,  
division Julius Centrum<br>  
Department of General Practice<br>  
Huispost Str. 6.131<br>  
PO Box 85500  
Bas Steunenberg  
Utrecht 3508 GA  
The Netherlands

## Eligibility criteria

### Inclusion criteria

1. A score of  $\geq 1$  on the Groningen Frailty Indicator (GFI);
2. Age 65 and over;
3. –Inhabitant of the community of Wijk bij Duurstede;
4. Living independently, in an assistant living apartment near the local nursing home or in the habitat WOZOCO or visitor of the Uitwijk.

### Exclusion criteria

1. Cognitively impaired (MMSE < 23 ; assessed at inclusion; pre-diagnostic interview);
- 2.–Severe immobility such as wheelchair dependent;
- 3.–Inability to communicate in Dutch.

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruiting

Start date (anticipated):	01-08-2012
Enrollment:	400
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	02-05-2013
Application type:	First submission

## 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
NTR-new	NL3814
NTR-old	NTR3980
Other	METC UMC Utrecht : 12-096
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A