

# A group version of Community Reinforcement and Family Training (CRAFT) compared to Self-Directed Delivery and to non-intervention: a three-armed Randomized Clinical Trial.

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In this research the effectiveness of CRAFT Group Training and CRAFT Bibliotherapy will be examined and outcomes will be compared with no intervention at all.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON44368

### Source

ToetsingOnline

### Brief title

CRAFT-study

### Condition

- Other condition
- Lifestyle issues

### Synonym

addiction, substance dependent loved one

### Health condition

Verslaving (indirect, via naasten van verslaafden), psychosociale klachten en algemene (psychische) gezondheid

## Research involving

Human

## Sponsors and support

**Primary sponsor:** Iriszorg

**Source(s) of monetary or material Support:** Iriszorg;instelling voor verslavingszorg

## Intervention

**Keyword:** Addiction, CRAFT, Family

## Outcome measures

### Primary outcome

2. CSO Quality of life:

- Physical health and complaints - Tic P, Rand-36, EuroQoL-5d, somatisatization-items of the MAP
- Psychological health and complaints - Dass-21, MINI, MATE
- Functioning - Tic P
- Quality of Life: CRA-HS, WHOQoL-Bref
- Quality of the Relationship - CRA-RHS, AVL
- Other psychological measures - self efficacy GSES, attachment/ interaction style ECR, social support SSI

### Secondary outcome

1. Cost effecivity - Tic P, Rand-36 en EuroQol-5D

## Study description

### Background summary

Familymembers of addicted people are under a lot of stress because of the addiction of their loved ones. Also, addicted individuals are frequently not

entering health care and/ or it usually takes a long time before they make the step towards help.

For this reason, the addiction has generally an enormous impact on the psychological and physiological health of family members.

Community Reinforcement and Family Training (CRAFT) is a training designed to reduce the stress of the family members and to engage resistant substance users into treatment by working with their partners or family members. The method can be used in both individual and group settings.

American research has demonstrated an improvement in wellbeing of partners or family members, a decrease in domestic violence and enormous increase in the engagement in treatment (about 2/3 of the substance users enters a treatment). In the Netherlands, research on CRAFT is never been done before.

## **Study objective**

In this research the effectiveness of CRAFT Group Training and CRAFT Bibliotherapy will be examined and outcomes will be compared with no intervention at all.

## **Study design**

In this RCT research the effectiveness of the CRAFT group training will be compared with Self-Directed CRAFT (Bibliotherapy) and a group without intervention. These groups will exist of partners or family members of treatment refusing addicts.

## **Intervention**

CRAFT is a CRA (Community Reinforcement Approach) based intervention. In this approach using different, incompatible and stronger reinforcers than drug or alcohol use are crucial.

By teaching how to (re)act facing with problems with the addicted individual and the addiction, CRAFT is increasing the quality of life of partners or family members. The main goal is that they are as little as possible (negatively) influenced by the addiction of their loved one, are becoming more active and do things they like themselves, learn to recognize how their behaviour can maintain the addiction and change these behaviours.

By a different communication style, changes in behaviour of the partner or family member and finding alternative activities and rewards when not using alcohol or drugs, CRAFT is increasing the quality of the relationship between the addicted persons and their loved ones, decreasing the amount of substance used and enlarges the amount of addicted persons entering treatment.

## **Study burden and risks**

The risk for negative side effect of this training is close to zero. The burden

for participants for answering questionnaires will be 4 x 60-70 minutes (4-5,5 hour).

The group training will take 7 x 90 minutes (=10,5 hours). Besides participant will get homework and exercises for their daily life.

Reading the self-help book will cost 10 hours in average.

Participants in the waiting list group, will be offered the CRAFT group training immediately after answering the last questionnaires (6 months after the initial questionnaires)

## Contacts

### **Public**

Iriszorg

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### **Age**

Adults (18-64 years)

Elderly (65 years and older)

## Inclusion criteria

Loved ones (non-addicts) of addicted persons who are not in treatment yet, age at least 18 years (loved one)

## Exclusion criteria

The loved ones will be excluded from the study if they meet the DSM-IV criteria themselves, if the addicted person received treatment (other than detoxification) for alcohol or drug problems in the prior three months, such as e-health, medication or any other outpatient or inpatient treatment, was mandated by the courts to receive treatment, or was currently motivated to accept treatment; and if the loved one has insufficient reading abilities to comprehend the self-help book and self-assessment packet (approximately 8th grade reading level).

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-08-2015
Enrollment:	105
Type:	Actual

## Ethics review

Approved WMO	
Date:	03-09-2014
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	29-07-2015
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)
Approved WMO	
Date:	28-06-2016
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

## 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	NL48307.028.14