Treatment effectiveness in multiproblem young adults

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21218

Source Nationaal Trial Register

Brief title

not applicable

Health condition

All multiproblem young adults (18-27 years old) referred to a (multimodal) treatment program by JOLO will be asked to participate. The Self-Sufficiency Matrix (SSM) is an instrument that is used as standard intake procedure by JOLO, to gain insight into the level of self-sufficiency and into problems in multiple areas of the young adults lives at the moment of intake, for example: shelter/housing, mental/physical health, income, employment, family relations, addiction, daily activities, social network, community involvement, justice (Culhane, Gross, Parker, Poppe, & Sykes, 2008; Fassaert, Lauriks, Weerd, Wit, & Buster, 2013; Lauriks et al., 2013). Scores range from 1 (acute problems with self-sufficiency) to 5 (excellent selfsufficiency) on each domain. We have developed an SSM definition for 'multiproblem young adults' based on the profile of the participants of DNK in the past years:

SSM multiproblem score:

-A score of 1 or 2 on the domains Income and Daily activities

- A score of 1, 2, or 3 on the domains Justice and/or Addiction and/or Mental Health and/or Social Network

- A score of 3, 4, or 5 on the domain Physical Health

Sponsors and support

Primary sponsor: VU Medical Center Amsterdam
Department of Child and Adolescent Psychiatry
Postbus 303, 1115 ZG Duivendrecht
Biesbosch 67, 1115 HG Duivendrecht
0031 20 8901545
Source(s) of monetary or material Support: Stichting de Verre Bergen
Westersingel 102
3015 LD Rotterdam
0031 10 2092000

Intervention

Outcome measures

Primary outcome

- Recidivism
- Self-sufficiency

Secondary outcome

- Quality of Life
- Psychosocial functioning
- Cognitive distortion
- Substance use
- Work or school

Study description

Background summary

We aim to study the effectiveness of a multimodal day treatment program (De Nieuwe Kans) for multiproblem young adults (between 18 and 27 years) and the participant- and treatment specific characteristics that are associated with treatment outcome. In close collaboration with a municipal facility for young adults (Het Jongerenloket) and several addiction, forensic and day treatment programs in Rotterdam, the Netherlands, we will apply a randomized

control trial (RCT) design to study 500 multiproblem young adults. This study is conducted for a period of three years, applying questionnaires, record and registration data, qualitative interviews and focus groups. The RCT study is part of a larger research program on multiproblem young adults.

Study objective

Background:

Multiproblem young adults (between ages 18 and 27), characterized by a variety of severe psychosocial problems, comprise a societal challenge with high priority on the political agenda, both nationally and internationally. However, so far the effectiveness of interventions in this group is largely unknown. Therefore, in-depth multidisciplinary research investigating the effectiveness of intervention in this population is urgently warranted.

Goal:

We aim to study the effectiveness of a multimodal day treatment program versus treatment as usual for multiproblem young adults and the participant/treatment specific characteristics that are associated with treatment outcome.

Study design:

In close collaboration with a municipal facility for adolescents and young adults ("Het Jongerenloket"; short "JOLO") and several (day) treatment programs in Rotterdam, the Netherlands, we will apply a randomized control design. In this study, 500 multiproblem young adults will be included to determine the treatment effectiveness (on recidivism and self-sufficiency) of the multimodal day treatment program De Nieuwe Kans (DNK) vs. treatment as usual (TAU). This study is conducted for a period of three years, applying questionnaires, record and registration data, qualitative interviews and focus groups, at four time points (T0, T1, T2, T3).

Study design

T0 - Baseline (before start intervention): Criminal background (WODC Self Reported Delinquency), Self-sufficiency (SSM), Quality of Life (MANSA), Psychological functioning/ psychopathology (ASR and MINI), Cognitive distortion (HIT), Substance use (MATE).

T1 (2 months after start intervention): Self-sufficiency (SSM), Quality of Life (MANSA), Cognitive distortion (HIT).

T2 (8 months after baseline (T0)): Recidivism (WODC Self Reported Delinquency), Selfsufficiency (SSM), Quality of Life (MANSA), Psychological functioning (ASR), Start working/attending school when intervention has ended, Cognitive distortion (HIT), Substance use (MATE).

T3 (14 months after baseline (T0)): Recidivism (WODC Self Reported Delinquency, record and registration data), Self-sufficiency (SSM), Quality of Life (MANSA), Psychological functioning (ASR), Start working/attending school when intervention has ended, Cognitive distortion (HIT), Substance use (MATE).

Intervention

Experimental condition - De Nieuwe Kans (DNK)

DNK is one the few multimodal day treatment programs available for multiproblem young adults in the Netherlands that offer an integrative approach to enhance self-sufficiency, improvement of quality of life, increase of motivation and provision of access to psychiatric services if indicated. The DNK program provides an integrated program of educational, work and care services. A team of coaches, teachers and social workers support the young adults to help them with their needs (e.g., financial problems), increase their self-sufficiency and skills, and help them return to formal education, work or (if necessary) mental health care. DNK is characterized by its small scale and the personal approach by the trainers. The content is tailor made to the individual's specific needs and the program length is flexible, with an average duration of 6 months. In general, the program consists of three main phases. In the initial phase of the program, self-sufficiency of the participants is mainly enhanced by offering support with practical needs, such as housing, financial debts, and receiving social security. Furthermore, motivation as well as an adequate day-night rhythm is developed. In the second phase of the program, self-sufficiency as well as motivation and self-esteem are further enhanced by specific (motivational) trainings and by improving learning and general worker skills. The program's educational component consists of courses in which the participants can obtain certificates. In the third and last phase of the program, self-sufficiency and motivation is consolidated and the participants focus on finding a job, an internship, or prepare to enroll (back) into an educational setting. Throughout the entire program the participants are professionally supported by social workers and (if necessary) a mental health care assistant. If a participant experiences severe mental health problems and/or addiction problems, a side trajectory is started in collaboration with a mental health care institution.

Control condition - Treatment as usual (TAU)

The control condition comprises several treatment as usual options that are available for multiproblem young adults that have been referred to JOLO. The two main options are: First, Aan de slag met zorg (ADSMZ) is a collaboration of the municipality of Rotterdam with several mental health care institutions and day programs for multiproblem young adults. After the intake at JOLO, a young adult with severe mental health issues (as assessed by the JOLO coach) who is allocated to the control condition will receive an intake with a psychologist of ADSMZ. After this intake a team of professionals from the several mental health care institutions and treatment programs decides which day program and/or mental health care program is suitable for the participant. Subsequently, the participant is enrolled in one of the treatment programs of ADSMZ, with a duration of approximately 6 months. Overall, the participant receives treatment for mental health problems in a mental health care institution, for example Lucertis Child and Adolescent Psychiatry. The treatment is tailor made to the specific needs of the participant and can vary from aggression regulation training to therapy for addiction problems.

Second, Challenge Sports is a multimodal day treatment program for multiproblem young adults without severe mental health issues. The average duration of Challenge Sports is somewhat shorter than DNK: 3 months for a complete trajectory, with a possibility of elongation for another 3 months. Challenge Sports uses professional athletes as teachers, roll models and coaches for the participants to enhance self sufficiency, motivation, and educational skills. After a short trajectory, participants are enrolled (back) in a educational or work setting.

Randomization procedure

During the T0 baseline measures the masking is triple blind: the researcher, the participant and the JOLO coach are blind for the treatment condition. After the T0 baseline measures, participants will be assigned randomly to the experimental condition (DNK) or to the control condition (TAU). At this point the masking is not blind anymore. The randomization is performed by a widely used online computer program (www.random.org). After this, the researcher will inform the participant's JOLO coach of the outcome of randomization. The coach will inform the participant to which program he will be allocated, during the second part of the JOLO intake. In case of randomization to the control condition, the coach decides which TAU-program is suitable for the participant.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Age: 18-27 years
- Gender: Male

- Sufficient knowledge of the Dutch language to understand the study procedure and to fill out the questionnaires

- An SSM multiproblem score:

-A score of 1 or 2 on the domains Income and Daily activities

- A score of 1, 2, or 3 on the domains Justice and/or Addiction and/or Mental Health and/or Social Network

- A score of 3, 4, or 5 on the domain Physical Health

Exclusion criteria

not applicable

Study design

Design

Study type: Intervention model: Interventional Parallel

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Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	24-07-2014
Enrollment:	500
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	17-04-2015
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-newNL5017NTR-oldNTR5163OtherMedisch Ethische Toetsingscommissie VU medisch centrum (METC VUmc) :
2013.422 - NL46906.029.13

Study results

Summary results not applicable

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