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The effectiveness of multidimensional family therapy (MDFT) versus cognitive behavioural therapy (CBT) in Dutch adolescents with a cannabis use disorder

Submission date
15/02/2011

Recruitment status
No longer recruiting

Registration date
17/03/2011

Overall study status
Completed

Last Edited
18/12/2020

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Study protocol nr. 1106812 of the Netherlands Ministry of Health, Welfare and Sports

Study information

Scientific Title
The effectiveness of multidimensional family therapy (MDFT) versus cognitive behavioural therapy (CBT) in Dutch adolescents with a cannabis use disorder: a randomised controlled trial

Study objectives
1. How effective is MDFT, compared to CBT, in reducing cannabis use and presence of a cannabis use disorder?
2. How effective is MDFT, compared to CBT, in attenuating the use of other psycho-active substances, internalising and externalising mental health and behavioural problems and delinquency?
3. How does the treatment retention of MDFT compare to CBT?
4. How does the satisfaction of the adolescents, parents and therapists about MDFT compare to CBT?
5. Which patient-characteristics are predictive of positive treatment-outcome in MDFT and in CBT and which patient-characteristic modify the treatment effect?
6. How do the costs of MDFT compare to CBT, in relation with the clinical results of both treatments?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Review Committee Mental Health Settings; METiGG (Medisch-ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg; METiGG), approved on 22nd December 2005, ref: 5238

Study design
Single centre open-label parallel-group randomised controlled intervention study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
DSM-IV cannabis use disorder

Interventions
Treatment in the control condition consists of five to six months outpatient CBT, focused on enhancing the patient's motivation to change his addictive behaviour and subsequently changing his maladaptive behaviours and cognitions by means of self control training, social and coping skills training and relapse prevention, based on the methods and treatment protocols of Miller and Rollnick (Miller and Rollnick, 1991), Kadden et al. (Kadden et al., 1992) and Monti and colleagues (Monti et al., 1989). Treatment is delivered by trained therapists who use a CBT treatment manual (De Wildt, 2002) and who are supervised during the course of the study by a highly experienced cognitive behavioral therapist. The treatment sessions are held with the individual adolescent on a weekly basis and with a duration of one hour each. In addition, a treatment session is scheduled once a month for the parents of the adolescent, with the goal to provide psycho-education and support and to discuss treatment progress of the adolescent. Notably, these sessions with the parents are support-oriented and not system-oriented.

Treatment in the experimental condition consists of five to six months outpatient MDFT. MDFT is a family-based and developmentally oriented treatment for adolescent substance use disorders and related problems, targeted at the functioning of the adolescents across four life domains: the adolescent as an individual, the relationship to his parents, the relationship to other family members and the relationship to extra-familial contexts of influence, such as school, work, anti-social and/or drug using peer networks and the juvenile justice system. MDFT-therapists have individual sessions with the adolescent alone and the parents alone, sessions with the family, and sessions with family members and influential extra-familial system representatives. The MDFT sessions with adolescent, parents or family are scheduled on average twice a week, in addition to sessions or contacts with school, courts, and other persons or parties. MDFT is delivered by trained and supervised therapists, who use the MDFT treatment manual developed by the original authors (http://kap.samhsa.gov/products/manuals/cyt). Given that MDFT is introduced in the Netherlands in the context of the present study, therapists and supervisors are trained by the original developers of MDFT at the Center for Treatment Research on Adolescence Drug Abuse (CTRADA) of the University of Miami School of Medicine (Liddle et al., 2002) prior to the start of the study. In addition, MDFT supervisors contact trainers from CTRADA on a monthly basis during the study to receive feedback and consultation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Study assessments take place at baseline and at three, six, nine and 12 months (end-point) following baseline.
1. Frequency of cannabis use (i.e. number of cannabis using days and number of joints smoked) in the 90 days preceding the month 12 assessment, based on the timeline follow back (TLFB) calender method. The study data are analysed using an intent-to-treat approach, in which all patients are included that were notified about their group allocation after randomisation.

Efficacy of MDFT vs CBT in terms of the primary outcome measure is analysed by means of a 2 (treatment group: MDFT vs CBT) x 2 (time: baseline vs month 12) repeated measures MANOVA, using the baseline and month 12 datasets.

Secondary outcome measures

1. The percentage of treatment responders at month 12-treatment responders are defined as participants who have at least 30% less cannabis using days in the 90 days preceding the month 12 assesment compared to baseline, provided that this reduction is not at the expense of a substantial increase (more than 6 days in the past month) in the use of other substances (i.e. alcohol (at least five glasses a day), cocaine, amphetamines and ecstasy). Adolescents are considered to be in recovery if they live in the community (as opposed to being incarcerated or in inpatient treatment) and are completely abstinent from cannabis, alcohol (at least five glasses a day) and any other substance use on each of the 90 days preceding the month 12 assessment.
2. The percentage of recovered adolescents at month 12
3. The number of property and violent crimes committed in the 90 days preceding the month 12 assessment
4. Treatment retention-Treatment retention is defined as the number of weeks that a treatment session was attended by the adolescent.

In addition, we calculate the total time of therapeutic contacts spent with the adolescent, parents and other family member or relevant extra-familial parties as an indicator of the total treatment dosage received. Adolescents are considered as treatment completers if they attended a treatment session in at least 75% of the planned number of treatment weeks. Based on a planned treatment duration of at least five months (22 weeks), this amounts to a minimum of 17 treatment weeks for both conditions. The difference in percentage of treatment responders between the study groups at month 12 is analysed in a logistic regression model, with treatment group as independent variable and treatment response as outcome variable. The same approach is used for analysing the difference in percentage of recovered adolescents at month 12. Differences in delinquent behaviour (property and violent crimes) between the study groups at month 12 are tested using the same analytical approach as described for the primary outcome measure (i.e. repeated measures MANOVA). Difference in treatment retention and in percentage of treatment completers between the study groups is tested in a multivariate linear regression and logistic regression analysis, respectively, with treatment group as independent variable. Finally, GeneraliSed Estimation Equation (GEE) is used to investigate whether the temporal course of cannabis use and delinquent behaviour differs between the adolescents in MDFT and those in CBT on each of the assessment points during the 12 months study period.

Overall study start date
01/03/2006

Completion date
01/11/2010

Eligibility

Key inclusion criteria
1. A history of cannabis abuse or cannabis dependency based on Diagnostic and Statistical Manual of Mental Disorders, 4th Edition (DSM-IV) in at least the year preceding the baseline assessment
2. Recent, regular use of cannabis, as indicated by self-reported cannabis consumption:
2.1. On two or more days a week during the three months preceding the start of the study
2.2. On two or more days a week during the three months preceding the entry of a controlled environment, provided that the controlled environment directly preceded the start of the study and started not longer ago than 90 days before the start of the study
3. Age ranging from 13 to 18 years
4. At least one (step) parent or legal guardian able and willing to participate in the treatment

and in the required study assessments
5. Written informed consent, by both the adolescent and his or her parent or legal guardian

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
N=128 (2 x 64 patients)

Total final enrolment
109

Key exclusion criteria
1. Mental retardation, acute psychosis or acute suicidality
2. Inpatient or opioid substitution treatment is required, according to clinical judgement
3. Living outside the catchment area of the treatment centre
4. Inability to understand the Dutch language
5. Participation in another trial aimed at reduction of psycho-active substance use or delinquent behaviour

Date of first enrolment
01/03/2006

Date of final enrolment
01/11/2010

Locations

Countries of recruitment
Netherlands

Study participating centre
Monsterseweg 83
The Hague
Netherlands
2553 RJ

Sponsor information

Organisation
The Netherlands Ministry of Health, Welfare and Sport (Netherlands)

Sponsor details
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Sponsor type
Government

ROR
https://ror.org/041evnj42

Funder(s)

Funder type
Government

Funder Name
The Netherlands Ministry of Health, Welfare and Sport (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2016	18/12/2020	Yes	No