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Multidimensional family therapy (MDFT) treatment of adolescents with substance use disorders, focusing on risk and protective factors in major youth life domains

Submission date
08/03/2010

Recruitment status
No longer recruiting

Registration date
17/03/2010

Overall study status
Completed

Last Edited
28/08/2018

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol
Not provided at time of registration

Study website
http://incant.eu

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IST0808

Study information

Scientific Title
The effectiveness of outpatient multidimensional family therapy (MDFT) compared with outpatient treatment as usual in adolescents with a cannabis use disorder and other problem behaviour: a multicentre, trans-national randomised controlled trial

Acronym
INCANT (International Cannabis Need of Treatment study)

Study objectives
Aim:
To examine if multidimensional family therapy (MDFT) is superior to treatment as usual in reducing substance abuse (notably cannabis) and other problem behaviour in adolescents. This is a multicentre trial, with sites in Brussels, Berlin, Paris, The Hague and Geneva.

Primary hypotheses:
1. Youths assigned to MDFT will diminish their use of cannabis more than youths in the treatment as usual condition between baseline and 4 follow-up assessments spaced across a 1-year follow-up period
2. Youths assigned to MDFT will be less likely to meet diagnostic criteria of cannabis disorders going from baseline to the 12 months follow-up assessment than youths treated as usual

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Belgium: Comité dÉthique Hospitalier approved on the 8th August 2006 (ref: CE2006/39)
2. France: Comité Consultatif de Protection des Personnes dans la Recherche Biomedicale approved on the 28th August 2006 (ref: 0611357)
3. Germany: Kammer für Psychologische Psychotherapeuten und Kinder- und Jugendlichenpsychotherapeuten im Land Berlin approved on the 19th September 2006
4. Netherlands: Medisch-ethische Toetsingscommissie Instellingen Geestelijke Gezondheidszorg (METiGG) approved on the 9th May 2006 (ref: 5238)
5. Switzerland: Association des Médecins du Canton de Genève et Societé Médicale Commission dEthique pour la Recherche Clinique en Ambulatoire approved on the 6th February 2007 (ref: 07-02)
6. USA (Miami): Institutional Review Board of University of Miami Miller School of Medicine, Human Subjects Research Office approved on the 21st September 2006 (ref: 20060330)

Study design
Multicentre phase III(b) randomised controlled trial with an open-label, parallel group design

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Can be found at http://incant.eu

Health condition(s) or problem(s) studied
Cannabis abuse and cannabis dependence

Interventions
MDFT:
4 - 6 months; sessions 2 - 3 times a week. Office-based and home-based sessions with:
1. The adolescent alone
2. The parent(s) alone
3. The family = adolescent + parent(s), and
4. Representatives of other social systems (friends, school, or probation) present

Treatment as usual (TAU):
This differs between countries to reflect local practice, but is based on cognitive-behavioural therapy and it matches MDFT in duration. In France and the Netherlands, TAU has been manualised.

Intervention Type
Other

Phase
Phase II/III

Primary outcome measure
1. MDFT reduces cannabis consumption more strongly than TAU in the 90-day periods preceding follow-up assessments points (a lower number of consumption days: TLFB = TimeLine Follow Back), the difference growing bigger over time
2. Number of urine tests indicative of cannabis use is lower in MDFT than in TAU at follow-up assessments points
3. In MDFT, youth show fewer (symptoms of) diagnoses of cannabis use disorders (as measured with the Adolescent Diagnostic Interview-Light [ADI-Light]) than in TAU at 12 months follow-up (the validated ADI-Light measures symptoms of substance use disorders). Assessment points: baseline, 12 months follow up.

Secondary outcome measures
1. MDFT reduces alcohol consumption to a greater extent than TAU, on the same measures and the same assessment points as outlined for cannabis
2. MDFT is superior to TAU in diminishing delinquent behaviour (less recidivism), as measured with the validated Adolescent and Parent Interviews, the Self-Reported Delinquency survey (SRD; lower score), lower scores on the delinquency sub-scales of Youth-Self Report (YSR) and its parent version, the Child Behaviour Checklist (CBCL). Also police and justice registration

databases. Assessment points: baseline, 6 months and 12 months follow up.
3. MDFT improves family functioning more than TAU (validated Adolescent and Parent Interviews using the Family Environment Scale [FES]). Interviews: baseline, 6 months and 12 months follow-up. FES: idem, but also 9-months follow up.
4. MDFT improves the youth's performance at school or work more than TAU (validated Adolescent and Parent Interviews, school reports, truancy logs). Assessment points: baseline, 6 months and 12 months follow up.

Overall study start date
01/08/2007

Completion date
01/08/2010

Eligibility

Key inclusion criteria
1. Age of the adolescent 13 through 18 years, either sex
2. Diagnosis of cannabis use disorder
3. At least 1 parent willing to take part in the treatment programme
4. Informed consent by both adolescent and parent(s)

Participant type(s)
Patient

Age group
Child

Lower age limit
13 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
480

Key exclusion criteria
1. Disorder requiring hospitalisation or other residential treatment
2. Intelligence Quotient (IQ) of adolescent below 70

Date of first enrolment
01/08/2007

Date of final enrolment
01/08/2010

Locations

Countries of recruitment
Belgium

France

Germany

Netherlands

Switzerland

Study participating centre
Viviënstraat 24
The Hague
Netherlands
2582 RT

Sponsor information

Organisation
Erasmus Medical Centre (Netherlands)

Sponsor details
c/o Dr Henk Rigter
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P.O. Box 2040
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3000 CA

Sponsor type
Government

Website
http://www.erasmusmc.nl/

ROR
https://ror.org/018906e22

Funder(s)

Funder type

Government

Funder Name
Federal Ministry of Health (Federaal Ministerie van Volksgezondheid) (Belgium)

Funder Name
Federal Ministry of Health (Bundesministerium für Gesundheit) (Germany)

Funder Name
The Inter-Departmental Mission for the Fight Against Drugs and Drug Addiction (Mission interministérielle de lutte contre la drogue et la toxicomanie [MILDT]) (France)

Funder Name
Ministry of Health, Welfare and Sports (Ministerie van Volksgezondheid, Welzijn en Sport [VWS]) (Netherlands)

Funder Name
Federal Office of Public Health (das Bundesamt für Gesundheit [BAG]) (Switzerland)

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?
Protocol article	protocol	09/04/2010		Yes	No
Results article	results	31/01/2014		Yes	No
Results article	results	17/08/2018		Yes	No