

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

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<b>Registration date</b> 17/03/2010	<b>Overall study status</b> Completed	<input checked="" type="checkbox"/> Protocol
<b>Last Edited</b> 28/08/2018	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

Not provided at time of registration

## Study website

<http://incant.eu>

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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The Hague  
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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 d'Éthique 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 Société Médicale Commission d'Éthique 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

Department of Public Health, Ae-233

P.O. Box 2040

Rotterdam

Netherlands

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?
<a href="#">Protocol article</a>	protocol	09/04/2010		Yes	No
<a href="#">Results article</a>	results	31/01/2014		Yes	No
<a href="#">Results article</a>	results	17/08/2018		Yes	No

