Internet gaming disorder in adolescents: a pilot study of Multidimensional Family Therapy (MDFT)

Recruitment status No longer recruiting	[X] Prospectively registered		
	[X] Protocol		
Overall study status	Statistical analysis plan		
Completed	[X] Results		
Condition category Mental and Behavioural Disorders	Individual participant data		
	No longer recruiting Overall study status Completed Condition category		

Plain English summary of protocol

Background and study aims

Worldwide, research and policy authorities acknowledge multidimensional family therapy (MDFT) as an effective treatment for adolescents with behavioral problems such as substance abuse and delinquency (criminal behaviour). MDFT is a type of behavioural treatment which improves the lives of adolescents and their families by targeting different areas of life. Treatment is organized into three stages: building a foundation for change, helping the patient and their family to change, and solidifying these changes. In recent years, both the Geneva and Paris MDFT teams have seen an increase of youth/families seeking treatment for adolescent Internet Gaming Disorder (IGD), an addiction to online gaming. These cases are being treated with MDFT, but more evidence about the effectiveness of MDFT in treating IGD is needed. The aim of this study is to investigate the effectiveness of MDFT in the treatment of IGD. The study takes place in Geneva, where adolescents receiving MDFT are compared to adolescents receiving standard family therapy, and in Paris, where all adolescents receive MDFT.

Who can participate?

Adolescents aged between 13 and 18 who are showing signs of gaming addiction and their parents.

What does the study involve?

In Geneva, participants are randomly allocated to one of two groups. Those in the first group take part in a six month programme of MDFT. The therapy is given in three stages, the first to motivate participants and create a treatment plan, the second to target the problem behaviour and improve family relationships and the third to seal off treatment and make a plan for what to do if the adolescent starts showing signs of gaming addiction. The therapy sessions involve an equal amount of sessions with the adolescent alone, with the parent(s) alone, and with the family (adolescent plus parents). The number of sessions per week can vary but on average there are two 30-90 minute sessions per week. Between sessions, the therapist keeps in regular contact with the adolescent and parent(s) through phone, email and other social media. Those in the second group receive family therapy as usual. The type of therapy varies and does not follow any specific stages. Sessions can take place anytime between once a week and once a month. At

the start of the study and then again after six and 12 months, adolescents and their parent(s) complete a number of questionnaires and are interviewed in order to assess how much the adolescent is gaming, their mental wellbeing and how they are doing in school. In Paris, all participants take part in the six month programme of MDFT. This involves the same methods used in the Geneva study and participants are also followed up after six and 12 months.

What are the possible benefits and risks of participating? Participants may benefit from reduced addictive behaviour (less Internet gaming), freeing time for more healthy behaviours. There are no known risks associated with participating.

Where is the study run from?

- 1. Fondation Phénix (Switzerland)
- 2. Centre Pierre Nicole, Croix Rouge Française (France)
- 3. Clinique Dupré (France)

When is the study starting and how long is it expected to run for? August 2016 to March 2020

Who is funding the study? Action Innocence (Switzerland)

Who is the main contact? 1. Dr Henk Rigter (public) 2. Mr Philip Nielsen (public)

Contact information

Type(s) Public

Contact name Dr Henk Rigter

ORCID ID http://orcid.org/0000-0003-0824-1207

Contact details

Curium, Department of Adolescent and Child Psychiatry Leiden University Medical Center P.O. Box 15 Leiden Netherlands 2300 AA

Type(s)

Public

Contact name Mr Philip Nielsen

Contact details

Fondation Phénix 21-23 Rue des Rois Geneva Switzerland 1204

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers MDFT-IGDv2

Study information

Scientific Title

Assessing the potential of Multidimensional Family Therapy (MDFT) and family treatment as usual to reduce Internet gaming and Internet gaming disorder in 13 to 18 years old adolescents from treatment sites in Geneva and greater Paris

Acronym

MDFT-IGD

Study objectives

Hypotheses:

 For the Geneva and Paris adolescents, Multidimensional Family Therapy (MDFT) will decrease the frequency of gaming going from baseline to 6 and 12 months follow-up
For Geneva, this decline will be larger for MDFT than for family treatment as usual (FTAU).
For the Geneva and Paris adolescents, MDFT will reduce the prevalence of the IGD diagnosis from 100% at baseline to significantly lower values at 6 and 12 months follow-up
In Geneva, IGD prevalence rate will drop more strongly for MDFT than for FTAU

In Geneva, the study is a randomised controlled trial (comparing MDFT and FTAU) and in Paris all participants receive FTAU. The Paris component has been added to aid the interpretation of the validity of the Geneva data.

Ethics approval required

Old ethics approval format

Ethics approval(s) Commission Cantonale d'Ëthique de la Recherche (CCER), 07/09/2016, ref: 2016-01344

Study design

Geneva: Multi-centre randomised controlled trial Paris: Single-group non randomised study

Primary study design

Interventional

Secondary study design

Randomised controlled trial and non-randomised study

Study setting(s)

Community

Study type(s)

Treatment

Participant information sheet

Not available in web format. Please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied

Internet Gaming Disorder (IGD)

Interventions

Geneva Study:

Participants are randomised to one of two groups using concealed randomisation procedures with database generated allocation to treatment group.

Intervention group: Participants receive Multidimensional Family Therapy (MDFT), an outpatient treatment programme lasting 6 months. MDFT is administered in three stages. The first one focuses on intensively enhancing treatment motivation, building multiple therapeutic alliances, and drafting the treatment plan. In stage 2, treatment plan interventions targeting the youth and his or her family are carried out, including education about adolescence, behavioural development, and risk factors for problem behaviour; relapse prevention; improving family communication and relationships; and strengthening parental educational skills. Stage 3 involves sealing off the treatment, agreeing on a relapse prevention plan, and providing booster sessions if needed. MDFT comprises three types of sessions:

- 1. Sessions with the adolescent alone
- 2. Sessions with only the parents (one parent [figure] or both parents)
- 3. Sessions with the family (adolescent plus parents)

These sessions are held in roughly equal proportion and last for 30 – 90 minutes. They may take place at the office of the treatment centre or at the family's home or any other convenient place. The number of sessions varies from week to week, but on average 2 sessions per week are held. In between sessions, the therapists use phone, email and other social media to remain in touch with adolescent and parents, to check if they adhere to actions agreed upon, and to encourage them.

Control group: Participants receive Family Therapy as Usual (FTAU). This involves family therapy best-practice procedures as taught locally (in Geneva) to systems-oriented therapists. The methods used are eclectic, combining elements from structural-strategic, narrative and solutionist family therapy. Unlike in MDFT, there are no specific treatment stages in FTAU. As in MDFT, alliance building and improving relations and communication within the family are common targets of treatment. Also in FTAU, three types of sessions are held, i.e. with the adolescent alone, the parents alone, and with the family, in roughly equal proportion. Treatment intensity is much lower for FTAU than for MDFT. Typically, the rhythm of sessions fluctuates between once a week and once a month. FTAU therapists are not actively working on their cases in between sessions, with the exception of monthly supervision sessions. As a result, FTAU therapists' caseloads are 3 to 4 times higher than MDFT therapist caseloads.

Follow up for all participants involves two assessments of gaming behaviour, mental health, family functioning and school functioning. The first of these assessments is at 6 months after baseline/allocation to treatment group, so at the time the treatments ends. The second one is at 12 months after baseline/allocation to treatment to treatment group.

Paris/Sceaux Study:

All participants receive Multidimensional Family Therapy (MDFT), which follows the same methodology as the MDFT in Geneva. Follow up is the same as in Geneva and therefore involves two assessments, i.e. at 6 and 12 months after baseline.

Intervention Type

Behavioural

Primary outcome measure

1. Frequency of gaming is measured using the TimeLine Follow-Back (FLFB) at baseline, 6 and 12 months

2. Prevalence of internet gaming disorder diagnosis is measured using the IGD consensus scale at baseline, 6 and 12 months

Secondary outcome measures

1. Mental health status and symptoms of the adolescent will be measured with the wellvalidated Youth Self-Report (YSR) and with the Rotterdam Well-being of Youth Scale (R-WYS) at baseline, 6 and 12 months

2. The parents' view of their child's mental health status and symptoms will be assessed with the well-validated Child Behavior Checklist (CBCL) and with the R-WYS, parent version, at baseline, 6 and 12 months

3. Family functioning/communication will be measured in the Adolescent Interview and Parent Interview at baseline and 12 months

4. Parental supervision is assessed in the Adolescent and Parent Interviews at baseline and 12 months

5. School functioning of the adolescent will be measured using the Rotterdam Well-being of Youth Scale (R-WYS) and Adolescent and Parent Interviews at baseline, 6 and 12 months

6. Treatment retention is assessed using treatment contact logs throughout the 6 months of treatment

7. Treatment adherence is measured through a random sample of MDFT family sessions (midway treatment: at 3 months) being recorded on tape/disc and analysed for adherence to MDFT principles, using the 16-item MDFT Adherence Scale

Overall study start date

01/08/2016

Completion date

01/03/2020

Eligibility

Key inclusion criteria

1. Adolescents aged 13 - 18 years old

2. Meeting 5 or more of the 9 criteria from the IGD consensus scale

3. At least one parent is willing to take part in the treatment and the study

4. Both adolescent and parent master the local language (French and English in Geneva, and French in Paris)

5, Informed consent by the adolescent and parent(s)

Participant type(s)

Other

Age group

Other

Sex Both

Target number of participants N = 80

Total final enrolment 42

Key exclusion criteria

Adolescents who require inpatient treatment because of psychosis, advanced eating disorder, or severe suicidal ideation.

Date of first enrolment 15/10/2016

Date of final enrolment 01/03/2019

Locations

Countries of recruitment France

Switzerland

Study participating centre Fondation Phénix 21–23 Rue des Rois Geneva Switzerland 1204 **Study participating centre Centre Pierre Nicole, Croix Rouge Française** 27, rue Pierre Nicole Paris France 75005

Study participating centre Clinique Dupré 30, Avenue Franklin Roosevelt Sceaux France 92333

Sponsor information

Organisation Fondation Wilsdorf

Sponsor details Place d'Armes 20 Carouge Switzerland 1227

Sponsor type Charity

Website www.agfa-ge.ch

Organisation La Loterie Romande

Sponsor details Case Postale 3375 Geneva Switzerland 1211

Sponsor type

Charity

Website www.entraide.ch/fr

Funder(s)

Funder type Charity

Funder Name Action Innocence

Results and Publications

Publication and dissemination plan

Recruitment will start in October 2016. The Final Report on the study will be ready by the end of December 2018. Publications will be submitted to journals in Spring 2019.

Intention to publish date

31/08/2020

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Henk Rigter. The request should be accompanied by a study proposal. If the data are relevant for the study proposed, Dr Rigter will advise Dr Marina Krokar, director of treatment centre Phénix in Geneva – the formal owner of the database – to give the researchers concerned access to the database under standard conditions (privacy, etc).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>		01/04/2021	28/04/2021	Yes	No
Protocol file	version 3	02/11/2017	09/11/2022	No	No