# Study plan: Internet gaming disorder in adolescents: a study of Multidimensional Family Therapy

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**SYNOPSIS OF THE STUDY PLAN**

## Synopsis of the study plan

Worldwide, research and policy authorities acknowledge that multidimensional family therapy (MDFT) is an effective treatment for adolescents with behavioural problems such as substance abuse and delinquency. This study's collaborating treatment centres in Geneva (Fondation Phénix) and Paris (sub-sites Pierre Nicole Croix Rouge, and Dupré Clinic) each avail of a MDFT team for more than 10 years now. These teams consist of experienced and certified MDFT therapists and MDFT supervisors.

In recent years, both the Geneva and Paris MDFT teams have seen an increase in adolescents/families seeking treatment for adolescent for excessive Internet gaming, provisionally called Internet Gaming Disorder (IGD). These cases are being treated with MDFT, but evidence that MDFT is effective in IGD is wanting.

In the study proposed here, we will examine MDFT's effects on primary IGD outcome measures, and on secondary outcome measures related to family functioning, parental supervision behaviour, and school attendance and performance by the adolescent. In Geneva, the study is a monocentre randomised controlled trial comparing MDFT with family therapy as usual, a common approach locally. All Paris IGD adolescents will be offered MDFT.

In MDFT, the therapist addresses not only the adolescent's thoughts and habits, but also risk and protective factors from important life domains of a youth, including family, friends, school, work, and leisure time activities. Therapy sessions are held with the adolescent alone, with the parent(s) alone, and with the family (adolescent plus parents), in roughly equal proportion. MDFT lasts 6 months. On average, there are two sessions a week, plus regular telephone and social media contact between the therapist and the adolescent, and idem with the parents. Key persons from the adolescent's social domains, e.g., teachers, may be invited to join family sessions. FTAU is less intense than MDFT, with 1 session a week (same type of sessions as in MDFT), and with no guidance by the therapist in between sessions.

Recruitment of cases will start as of December 2016, and will continue through May 2018. An adolescent, 12 to 19 years of age, will be included in the study if he or she meets at least 5 of the 9 DSM-5 IGD criteria, if at least one parent is willing to take part in the treatment and the study, and if both adolescent and parent(s) sign the informed consent form. We will recruit 60 cases in Geneva, to be randomised to MDFT (N=15) and FTAU (N=45), and 25 cases in Paris (all MDFT).

An adolescent will be excluded if he or she is requiring inpatient treatment because of psychosis, advanced eating disorder, or severe suicidal ideation.

Adolescents will be interviewed and asked to complete questionnaires at Baseline (right before the start of treatment), 6 months later (at the time the treatment ends), and 12 months later.

Our primary hypotheses pertain to gaming behaviour and to the diagnosis of IGD.

**Prevalence of the IGD diagnosis**

- For the Geneva and Paris adolescents, we predict that 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, the IGD prevalence rate will drop more strongly for MDFT than for FTAU.

**Frequency of gaming (hours a day)**

- For the Geneva and Paris adolescents, we assume that MDFT will decrease the frequency of gaming (gaming hours) going from baseline to 6 and 12 months' follow-up.
- For Geneva, we further assume that this decline will be larger for MDFT than for FTAU.

# 1 Background

## 1.1 Introduction

Quite a few adolescents spend much more time on using Internet services than the maximum advised by health authorities. In Switzerland, a 2012 federal Government report predicted a continuing rise of uncontrolled, excessive Internet use by children, including adolescents. This poses a risk to public health if no effective interventions would be undertaken. [1] In 2015, almost all Swiss adolescents had a smart phone, allowing access to Internet. Half of them regularly played Internet games. [2] In the recent Pelleas survey among more than 2000 high school pupils and college students in the Paris area, 14% were problematic users of Internet games. [3] Of the 17-year old respondents, 5% was involved in Internet activities for 5 to 6 hours a day, way beyond the maximum of 2 hours recommended by the American Academy of Pediatrics. [3] In other studies, prevalence rates of 'Internet addiction' among adolescents ranged from 3% to 8% or even higher. [4,5]

Frequent use of Internet may have pathological features. Just referring to 'Internet' or 'screen use' is not helpful from a therapy point of view. Here, we focus on Internet gaming. Many adolescent boys and girls take part in this activity. Some of them will develop Internet Gaming Disorder (IGD), a condition provisionally acknowledged in DSM-5 (fifth revision of the Diagnostic Statistical Manual). [6]

Adolescents with IGD often present with other mental disorders as well. Notably, they score high on indices of internalizing behaviour problems (depression and anxiety), including social phobia. [3]

A common therapy for IGD is cognitive behavioural therapy (CBT). From substance abuse and delinquency studies, we know that family treatment will result in better outcomes than CBT, with a particularly good record for Multidimensional Family Therapy (MDFT). [7,8] A systems perspective will allow the therapist to address not only the adolescent's thoughts and habits, but also risk and protective factors from important life domains of a youth, including family, friends, school, work, and leisure time activities. For instance, lack of parental monitoring of the adolescent's Internet activities and inadequate school responses to behaviours such as truancy, day dreaming, and seeking access to computer services contribute to the development and persistence of IGD. [9-11]

In earlier research, MDFT has been found to reduce substance abuse and delinquency in youths. [12-14] Most adolescents featuring in these investigations had multiple behavioural problems, including mental co-morbidity. These coexisting problems did not interfere with MDFT's effect; on the contrary. MDFT has been shown to diminish co-morbidity. [13, 14] Part of this earlier research was INCANT, a multisite randomised trial in five Western-European countries, including the sites featuring in the present study, targeting adolescents with cannabis use disorders.

The current study will be carried out at two locations, i.e., in Geneva and Paris. Unlike in Paris, MDFT is not the sole family treatment programme in Geneva to be considered for treating adolescents with IGD. Phénix also offers a more general form of family treatment – here called family treatment as usual (FTAU). Although both MDFT and FTAU are standard clinical practice, little is known about their individual and comparative effectiveness in diminishing problematic gaming behaviour.

**Objectives**

The aim of the present study is to examine the effectiveness of MDFT in a pooled cohort of IGD cases from Geneva and Paris, and to compare MDFT and FTAU outcomes at the Geneva site.

The non-controlled Paris part of the study serves to assess if Paris IGD adolescents respond to MDFT as well as Geneva adolescents are expected to do.

1.2 Title of the study

Internet gaming disorder in adolescents: a study of Multidimensional Family Therapy.

1.3 Short title

MDFT-IGD

1.4 Trial registry and ethical approval

Registry:

ISRCTN 11142726

Ethical approval:

Commission Cantonale d'Ethique de la Recherche (CCER); 2016-01344 Avis A1 27sept16

1.5 Type of study

This is a treatment effectiveness study at two clinical sites, in Geneva and Paris, evaluating ongoing treatment approaches for adolescents with Internet Gaming Disorder (IGD). Assessments will be pre-and post MDFT in Geneva and Paris, and in Geneva also between treatments: MDFT versus FTAU.

The Geneva component of the study is a phase III(b) randomised controlled effectiveness trial with an open-label, parallel group design.

1.6 Funding

For Switzerland, the main supplier of money to finance our study is the NGO Action Innocence (actioninnocence.org), a non-profit organisation promoting children's dignity and integrity on the Internet. The private Swiss foundations of Rolex-Wilsdorf, Divesa and the Loterie Romande in Switzerland have provided additional funds.

Main funding source in France is Française les Jeux.

The funding agencies have (had) no role in the design of this study; in the collection, management, analysis, and interpretation of the data; and in the writing of any publications resulting from this research.

## 2 Study hypotheses

2.1 Primary hypotheses: effect of treatment on Internet gaming/Internet Gaming Disorder

Our study's primary outcomes are a decrease in Internet Gaming Disorder (IGD) and in

Internet gaming hours.
Internet gaming = hours spent gaming on the Internet, alone or as part of a (virtual) group, plus time observing other gamers play, for instance, through You Tube vlogs.

Most important aim is to reduce problematic gaming, so to lower the prevalence of the IGD diagnosis. Gaming can have positive functions for the adolescent, such as boosting self-esteem and having social contacts. Some games require daily playing by the participant to avoid being banned from the playing group or to avoid dropping from the performance level achieved. Therefore, it is unrealistic to expect adolescents to stop gaming all together. The treatment aim should be to restore an adolescent's control over his or her playing behaviour, by having him or her opt for less time-demanding games or for shorter stretches of gaming. This will result in a decrease in the number of hours spent on gaming.

We will use three measures of gaming behaviour:

**Prevalence of the IGD diagnosis**

- For the Geneva and Paris adolescents, we predict that 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, the IGD prevalence rate will drop more strongly for MDFT than for FTAU.

**Number of IGD symptoms**

The IGD diagnosis is based on the number of IGD symptoms (criteria) met out of a total of 9.

- We expect MDFT to lower the number of IGD symptoms going from baseline to 6 and 12 months' follow-up, with MDFT outperforming FTAU in Geneva.

**Frequency of gaming (hours a day)**

- For the Geneva and Paris adolescents, we assume that MDFT will decrease the number of gaming hours going from baseline to 6 and 12 months' follow-up.
- For Geneva, we further assume that this decline will be larger for MDFT than for FTAU.

2.2 Secondary hypotheses

Many adolescents entering treatment for IGD will show symptoms of mental disorders, particularly internalising disorders.

- We expect MDFT to decrease the number of symptoms of internalising disorders over time, from baseline to 6 and 12 months' follow-up, with MDFT outperforming FTAU in Geneva.

IGD will lead to problems at school (truancy, failing exams).

- We assume that MDFT will reduce the adolescent's school problems over time, from baseline to 6 and 12 months' follow-up, with MDFT outperforming FTAU in Geneva.

MDFT is thought to exert its beneficial effects on adolescent behaviour through improving family communication and relationships.

- We predict that MDFT will improve family communication and family relationships over time, from baseline to 6 and 12 months' follow-up, with MDFT outperforming FTAU in

Geneva.

- We expect treatment to help parents to better engage with their child and to enforce home rules to curtail his or her Internet gaming behaviour. We assume that these positive effects on engagement and on setting home rules will grow over time, and that they will be stronger for MDFT than for FTAU in Geneva.

2.3 Treatment retention

- In Geneva, we expect MDFT to better retain adolescents and parents into treatment than FTAU. We predict that >80% of MDFT cases will be retained in treatment.

2.4 Satisfaction with treatment received (adolescents and parents)

- At the end of treatment, at 6 months' follow-up, both adolescents and parents will be asked if they were satisfied with the treatment received. We expect the satisfaction score to be higher for MDFT than for FTAU in Geneva, and to be equally high for MDFT Geneva and MDFT Paris.

2.5 Treatment adherence

MDFT treatment adherence will be measured as in earlier U.S. and European trials.

- The MDFT-IGD treatment adherence score will be as high as in earlier MDFT trials.

# 3 Timeline of the study

3.1 Recruitment of cases

Recruitment will start in December 2016 and will continue through May 2018. Treatment will start within 1 month of recruitment.

**First contact**

The first contact person for cases referred or self-referred to the Geneva or Paris treatment agencies will be the secretary, S. Privet in Geneva, and L. Roussel in Paris (who will oversee both Paris sub-sites; § 4.1). The secretary will ask at least one **screening question** (but usually a series of questions): Is there a problem, or might there be a problem, with Internet gaming? If the answer is yes and the case – adolescent and at least 1 parent – shows up for the first appointment, the secretary will assign a study code to the case. G001 for the first case in Geneva, followed by G002, and so on. P001 in Paris (irrespective of sub-site), et cetera.

**Intake by medical director (Geneva) or MDFT therapist (Paris/Sceaux)**

The first appointment of a possible IGD case is with medical director M. Croquette Krokar in Geneva, and with MDFT therapist O. Phan, N. Bastard, or C. Bonnaire in Paris. The professional concerned uses the *Internet Gaming Disorder consensus scale* (Appendix A) to assess if IGD is present, and the *Recruitment Flow* Chart (Appendix B) to check the other inclusion and the exclusion criteria for the adolescent and parent(s) (apart from informed consent yet). Also, the director/therapist fills out the Referral form (*Sources d'admission*; Appendix C).

**Inclusion criteria** (see also § 6.2)

- A boy or girl of 12 to 19 years of age
- Meeting at least 5 of the 9 DSM-5 IGD criteria
- At least one parent is willing to take part in the treatment and the study.
- Both adolescent and parent(s) sign the informed consent form (not at intake, though, but at the time of the Baseline assessment).

**Eligible cases**

If the case is eligible, the director/therapist will tell the family about the study. Topics to cover:

- What is IGD and why is it important to seek treatment for IGD?
- There are promising therapies for IGD. In Geneva: refer to MDFT and FTAU. In Paris/Sceaux: refer to MDFT.
- Why is it important to prove that a treatment really works (acceptance by the treatment centre, by insurance companies, and by the Government)? In Geneva: Why comparing MDFT with FTAU? In Paris: Why is it important to have therapist performance assessed?
- Benefits and requirements for taking part in the study.

The director/therapist gives the family member study information materials and an unsigned informed consent form to take home to read and consider. The director/therapist immediately arranges a meeting between the family members and the research assistant. In this meeting, the informed consent form will be signed, and the Baseline assessment will be carried out.

**Excluded cases**

For exclusion criteria, see § 6.3. Excluded cases will be referred to other treatment centres (in Geneva) or will be offered treatment outside the study at the site itself (Paris/Sceaux).

## 3.2 Baseline assessment

The Baseline assessment meeting starts with the research assistant answering any remaining questions the family may have about the study and with signing the informed consent form (to be signed by the adolescent, the parent[s], and the research assistant).

During the remainder of the Baseline assessment, the adolescents and parent(s) will be asked to complete questionnaires and to take part in a brief interview (see chapter 7). In Geneva, the session ends with the randomisation decision: allocation of the case to either MDFT or FTAU (§ 7.3).

## 3.3 Treatment

Treatment will last for 6 months.

## 3.4 Follow-up assessments

The first follow-up assessment will be at 6 months after the Baseline session, close to the moment of completion of the treatment, and the second one at 12 months after Baseline.

### 3.5 Statistical analyses

These analyses will start right after the data for the last recruited case has been inputted into the database, and they will take 3 months to complete.

### 3.6 Summary table

The study will run from December 2016 till early Summer in 2019.

See the table.

| **Stage** | **First case** | **Last case** | **Who?** |
|---|---|---|---|
| **Recruitment** | December 2016 | May 2018 | Research assistants |
| **Treatment** | Start: January 2016<br>End: June 2017 | Start: June 2018<br>End: November 2018 | Therapists |
| **Follow-up** | 6-mo FU: May 2017<br>12-mo FU: October 2017 | 6-mo FU: October 2018<br>12-mo FU: March 2019 | Research assistants |
| **Analyses and reporting** | March - June 2019 | | J. Dercksen<br>C. Henderson |

## 4 Treatment sites and therapists

### 4.1 Sites

- Geneva, Switzerland: Fondation Phénix
- Paris, France: two sub-sites, i.e., Centre Pierre Nicole, Croix Rouge Française, Paris; and Clinique Dupré, Sceaux

### 4.2 Therapists

In Geneva, 3 MDFT therapists (P. Nielsen, C. Soria, E. Wark). One of them (P. Nielsen) is also the supervisor of the MDFT team.

In Geneva, 3 FTAU therapists (S. Capuccio, C. Merino, A. Véron), supervised by F. Ritz.

In Paris, 3 MDFT therapists (N. Bastard, C. Bonnaire, O. Phan), supervised by O. Phan.

## 5 Treatments

### 5.1 MDFT

MDFT is an outpatient treatment programme for adolescents displaying problem behaviour.

The term 'multidimensional' means that each major domain in the life of an adolescent is thought to contribute to the incidence and persistence of behavioural problems (through risk factors). Each domain is also seen as potentially helpful in resolving the behavioural problems (through protective factors). The life domains include the youth him- or herself, parents, family, friends and peers, school and work, and leisure time.

MDFT consists of 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.

In earlier MDFT trials, MDFT was based on a manual. [13] This manual will be used in the current study as well, but with additions to accommodate the characteristics of IGD (rather than substance abuse and delinquency, the focus of previous trials). These additions are based on analysis of videotaped treatment sessions and the clinical experience of study team members P. Nielsen, O. Phan, N. Bastard, and H. Liddle.

**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 (1:1:1).

Sessions last for 30 – 90 minutes. They may take place at the office of the treatment centre, at the family's home, or any other convenient place.

Key persons from the social domains of the adolescent may be invited to join one or more family sessions, e.g., a teacher or a friend. Inviting teachers is important to help achieve the adolescent's treatment goals regarding school performance.

**Number of sessions**

The number of sessions may vary from week to week, but on average 2 sessions per week are held.

**Planning of sessions**

MDFT therapists carefully plan each session. The plan for a session includes the topics to be addressed linking to earlier sessions, and the goals to be achieved right now. The therapist notes down the session results.

**In between sessions**

The therapist uses phone, email and other currently used social media to remain in touch with adolescent and parents, to check if they adhere to actions agreed upon, and to encourage them.

### 5.2 Family Therapy As Usual (FTAU)

FTAU comprises best-practice procedures as taught locally to systems-oriented therapists. The methods used are eclectic, combining elements from structural-strategic, narrative and solutionist family therapy.

FTAU has not been developed specifically for teen addictions and behavioural problems. The approach focuses on enhancing family communication skills and emotional bonding.

There are no specific treatment stages. Alliance building and improving relations and communication within the family are common targets of treatment.

**Three types of sessions**

As in MDFT, sessions are held with the adolescent alone, the parents alone, and with the family, in roughly equal proportion.

**Number of sessions**

Treatment intensity is lower for FTAU than for MDFT. Typically, 1 session per week is being held in FTAU.

**Planning of sessions**

There is no specific planning of sessions in FTAU.

**In between sessions**

FTAU therapists are not actively working on their cases in between sessions, except for monthly supervision sessions. Thus, FTAU therapists' caseloads are 3 to 4 times higher than MDFT therapists' caseloads.

### 5.3 Treatment reimbursement

In Geneva, MDFT is being paid from research funds, and FTAU from regular health insurance funds. Families need to co-pay 10% for FTAU, as required by Swiss regulations. For comparability reasons, we will require 10% co-payment for MDFT as well.

In Paris, all treatment with MDFT is fully reimbursed by health/social insurance funds.

## 6 Study participants

### 6.1 Number

In Geneva, we will recruit 15 IGD adolescents, plus their parents, for the MDFT condition. This is 1 case per month, which is feasible. Per month, about 3-5 new IGD cases are seen at Phénix.

In Geneva, we will recruit 45 IGD cases for FTAU.

In Paris/Sceaux, we will recruit 25 IGD cases to be treated with MDFT. There is no comparison treatment available in Paris/Sceaux.

### 6.2 Inclusion

Cases will be included in the study, irrespective of the referral source – self-referred or third-party referred –, when the adolescent meets the criteria for IGD. The IGD scale contains 9 criteria/symptoms of IGD. [16] The adolescent must meet at least 5 of these criteria to be 'diagnosed' with IGD.

Additional requirements are:

- At least one parent is willing to take part in the treatment and the study.
- Both adolescent and parent master the local language (French and English in Geneva, and French in Paris).
- Informed consent by the adolescent and parent(s).

### 6.3 Exclusion

Adolescents will be excluded if they are requiring inpatient treatment because of psychosis, advanced eating disorder, or severe suicidal ideation.

Having been treated in the past for IGD or another condition, is not a reason to exclude a youth. However, we will not recruit adolescents who are currently receiving treatment for addiction-related issues in other mental health, addiction, or youth care facilities.

## 7 Assessments, informed consent, allocation to treatment

### 7.1 Assessments

- Baseline
- 6-Months follow-up (6 months from Baseline)
- 12-Months follow-up (12 months from Baseline)

### 7.2 Baseline

The Baseline session starts with the research assistant answering any remaining questions the adolescent and parent(s) may have about MDFT-IGD or about informed consent.

**Asking for informed consent**

Having answered these questions, the research assistant invites the adolescent and at least one parent to sign the informed consent form. She herself will sign the form, too.

**No informed consent**

What if the adolescent and/or parents refuse to give informed consent?

If the family members need more time to decide, they can be given two weeks' respite.

If informed consent is refused, the case will be excluded, and the Baseline session will be aborted.

### 7.3 Allocation to treatment

In Geneva, allocation to treatment is random and concealed. Cases will be randomly assigned to MDFT or FTAU, in a proportion of 1:3.

Cases are numbered. For each number, the MDFT-IGD database will automatically assign a treatment (MDFT or FTAU). At the end of the Baseline assessment, the research assistant will retrieve the allocation decision and tell the adolescent and parent(s) the result. The research assistant cannot modify the randomisation outcome, nor can anyone else.

### 7.4 Meeting the therapist

In *Geneva*, secretary S. Privet knows which therapist is first available to take the included case into treatment. Right after the Baseline assessment, while adolescent and parents are still present, the research assistant (M. Schoepf) will ask S. Privet for the name of this therapist. If the therapist concerned is present in the building, the family members are introduced to the therapist right away.

Before the family leaves home, S. Privet will schedule the first appointment with the therapist.

In *Paris*, the therapist seeing the case in the Recruitment session (§ 3.1) will treat the case with MDFT. The secretary (L. Roussel) will schedule appointments for both sub-sites, Pierre Nicole and Dupré.

### 7.5 Masking

When conducting the follow-up assessments, the research assistant In Geneva will be masked regarding the treatment to which the case was assigned.

## 8 Measurements

### 8.1 Recruitment

- *IGD consensus scale*. [16] To establish if the adolescent has IGD or not. Period covered: the 3 months preceding the assessment. See Appendix A.
- *Recruitment Flow Chart*, to check if (other) inclusion or exclusion criteria are being met. See Appendix B.

### 8.2 Baseline

The Baseline assessment takes 70 minutes.

**Minutes 0 – 10: Informed consent** (in the presence of adolescent and parents)

The research assistant answers remaining questions about the study. The informed consent form is being signed.

**Minutes 10 – 25 Personal and sociodemographic data** (adolescent; parents moved to another room)

- *Contact details* (where and how is the adolescent to be reached?)
- An IGD-adapted version of the *Adolescent Interview* as used in INCANT. The research

assistant interviews the adolescent in the absence of the parents.

Topics include age, gender, ethnic background; gaming issues, substance use, criminality, school, and work problems; peers, leisure time activities; mental health, addiction, delinquency problems of the parents. Period covered: the preceding 3 months.

**Minutes 25 – 35: Frequency of gaming behaviour** (adolescent)

Self-report by the adolescent. We have adapted the *TimeLine Follow-Back* (TLFB) method for use in IGD. Adolescents are asked to mark on a calendar spanning the last 90 days before the assessments, on which days they accessed the Internet for gaming purposes. More informative, for each day they will be asked to note down the number of hours spent on Internet gaming.

The research assistant helps the adolescent to complete the TLFB by providing structure and explanation.

Gaming is defined as: playing individual games or playing games as part of a group, and watching other people play games to learn from them.

**Minutes 35 – 45: Personal and sociodemographic data** (parents; separate room)

- *Contact details* (see above)
- An IGD-adapted version of the *Parent Interview* as used in INCANT. The research assistant interviews the parent(s) in the absence of the adolescent.

**Minutes 45 -55: Symptoms of mental/behavioural disorders** (adolescent and parents; separate rooms)

- Adolescents: we will deliver selected sections of the *Youth Self-Report* (YSR).
- For parents, we will administer selected sections of the *Child Behavior CheckList* (CBCL).
- As the French Pelleas study suggested that IGD youth may have increased levels of *social phobia*, we will ask the adolescents to respond to Questions 53 and 54 from the Pelleas survey. [3]
- In all cases: period covered = the preceding three months.

**Minutes 55 -65: Quality of life**

- A recent MDFT cost-effectiveness analysis [19] yielded a new quality of life scale, the validated R-WYS (Rotterdam Well-being of Youth Scale). In six items, on a 5-point scale, it taps six domains: substance use/addictive behaviour; school; work; family; social relations, peers; Justice.
- We will use the same scale for parents to give their impression on the adolescent's quality of life.
- Period covered = the preceding three months.

8.3 Six months' follow-up (time frames the same as for Baseline)

**Adolescents**

- IGD consensus scale

- IGD-adapted TLFB
- YSR
- Pelleas questions about social phobia
- R-WYS, adolescent version
- Treatment satisfaction: the summary question of INCANT's treatment satisfaction questionnaire

**Parents**

- CBCL
- R-WYS, parent version
- Treatment satisfaction: the summary question of INCANT's treatment satisfaction questionnaire

8.4 Twelve months' follow-up (time frames the same as for Baseline)

**Adolescents**

- Adolescent Interview
- IGD consensus scale
- IGD-adapted TLFB
- YSR
- Pelleas questions about social phobia
- R-WYS, adolescent version

**Parents**

- Parent Interview
- CBCL
- R-WYS, parent version

8.5 Treatment retention

As in INCANT [18], with the same checklist, we will monitor drop-out from and retention in treatment.

In a first approach, drop-out is defined as stopping with treatment within three months of the start of the therapy. Reasons for stopping (adolescent-initiated, parent-initiated, therapist-initiated) will be recorded.

Secondly, we will ask the therapists, using the corresponding INCANT form [18], if treatment was continued long enough to meet treatment goals, or was aborted before treatment goals were met.

8.6 Treatment adherence

For each Geneva and Paris MDFT case, the therapist concerned needs to forward a middle-treatment family session recording to Stichting Jeugdinterventies in the Netherlands, where adherence to MDFT principles will be independently assessed using the well-validated 16-item MDFT Adherence Scale. [18]

8.7 Summary table

| **Assessment** | Baseline | During treatment | 6-months Follow-up | 12-months Follow-up |
|---|---|---|---|---|
| Adolescent Interview | x | | | x |
| Parent Interview | x | | | x |
| IGD scale | x | | x | x |
| TLFB | x | | x | x |
| YSR, Youth Self-Report | x | | x | x |
| Pelleas, social phobia | x | | x | x |
| CBCL | x | | x | x |
| R-WYS adolescent | x | | x | x |
| R-WYS parent | x | | x | x |
| Treatment satisfaction adolescent | | | x | |
| Treatment satisfaction parent | | | x | |
| Treatment Contact Logs | | x | | |

Note

All forms/questionnaires and interviews are available in a document, which can be obtained from H Rigter.

Publications on the validity and reliability of the measures used are referenced in [12] and [18].

## 9 Data management and data analyses

9.1 Confidentiality

All data will be treated confidentially and will be processed anonymously.

The secretary will assign each case a unique study number. This number will not contain initials, date of birth, or other identifying variables.

The numbers will be linked to the contact details of each case (to be stored under lock, in a space only accessible by the research assistant).

The research assistant will input information on the case (from questionnaires and interviews) into the study's Internet-based central database. Database manager is researcher J. Dercksen.

The research assistant can access the inputted data from her or his own site, but not from the other site.

Inputted data can only be corrected with the consent of the research supervisor, H Rigter.

We will use the same data privacy protection protocol as in the cited INCANT study (approved by six ethical committees). [12] This protocol also pertains to data storage procedures.

### 9.2 Power

Power was assessed in the INCANT study using Monte Carlo techniques combined with Latent Curve Growth Modelling. [17] With 60 Geneva cases, MDFT was expected to yield bigger treatment effects than treatment as usual. This was confirmed in the INCANT trial. For the current study, we again opted for 60 Geneva cases, and for an additional 25 Paris cases. From our previous experience, we expect to find significant treatment differences.

### 9.3 Missing data

Study participants will be intensively tracked, as was successfully done in INCANT, with 90% completed assessments achieved at 12 months' follow-up. [18]

Missing items from multi-item scales will be imputed using a Gibbs sampler if less than 20% of items is missing. Otherwise, the whole scale will be considered missing.

### 9.4 Statistical analyses

The Geneva and Paris data will be pooled with site as covariate.

For cross-sectional analyses, we will use the $\chi^2$ test for categorical variables, and analysis of variance for continuous variables.

To assess changes over time, with sites and treatments as variables, we will use Latent Curve Growth Modelling (LGM), as we did before in INCANT. [17] The analyses will be based on the intention-to-treat approach.

Competing interests

PN, OP, HR, HL, and CH have been involved in one or more earlier trials of MDFT. Apart from that, they and the other team members report no financial or other competing interests.

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# APPENDIX A

## Internet Gaming Disorder consensus scale (les derniers 3 mois)

1. Passez-vous beaucoup de temps à penser aux jeux vidéo, y compris quand vous ne jouez pas, ou à prévoir quand vous pourrez jouer à nouveau?

   Oui Non

2. Lorsque vous tentez de jouer moins ou de ne plus jouer aux jeux vidéo, ou lorsque vous n'êtes pas en mesure de jouer, vous sentez-vous agité, irritable, d'humeur changeante, anxieux ou triste?

   Oui Non

3. Ressentez-vous le besoin de jouer aux jeux vidéo plus longtemps, de jouer à des jeux plus excitants, ou d'utiliser du matériel informatique plus puissant, pour atteindre le même état d'excitation qu'auparavant?

   Oui Non

4. Avez-vous l'impression que vous devriez jouer moins, mais que vous n'arrivez pas à réduire votre temps de jeux vidéo?

   Oui Non

5. Avez-vous perdu l'intérêt ou réduit votre participation à d'autres activités (temps pour vos loisirs, vos amis) à cause des jeux vidéo?

   Oui Non

6. Avez-vous continué à jouer aux jeux vidéo, tout en sachant que cela entraînait chez vous des problèmes (ne pas dormir assez, être en retard à l'école/au travail, dépenser trop d'argent, se disputer, négliger des choses importantes à faire)?

   Oui Non

7. Vous arrive-t-il de cacher aux autres, votre famille, vos amis, à quel point vous jouez aux jeux vidéo, ou de leur mentir à propos de vos habitudes de jeu?

   Oui Non

8. Avez-vous joué aux jeux vidéo pour échapper à des problèmes personnels, ou pour soulager une humeur dysphorique (exemple: sentiments d'impuissance, de culpabilité, d'anxiété, de dépression)?

   Oui Non

9. Avez-vous mis en danger ou perdu une relation affective importante, un travail, un emploi ou des possibilités d'étude à cause des jeux vidéo?

   Oui Non

## APPENDIX B

## Recruitment Flow Chart MDFT-IGD

| **Case Code _____** | **Inclusion** | **Exclusion** |
|---|---|---|
| Age 12 through 19 years | Yes | No |
| Adolescent and at least 1 parent speak/understand the local language | Yes | No |
| Adolescent has Internet Gaming Disorder | Yes | No |
| At least 1 parent available for taking part in the treatment | Yes | No |
| Inpatient treatment needed | No | Yes |
| Adolescent is receiving other treatment for gaming | No | Yes |

To be dealt with later:

| | | |
|---|---|---|
| Informed consent by the Adolescent | Yes | No |
| Informed consent by at least 1 Parent | Yes | No |

# APPENDIX C

## Sources d'admission

**Code Adolescent: G/P _ _ _ Date Interview: _____**

Prière d'encercler la réponse appropriée (☞ plusieurs réponses possibles)

**Par qui l'adolescent a été envoyé ?**

1 Lui-même

2 Ses parents

3 Des amis

4 Autre famille ou connaissances

5 Le milieu scolaire

6 Un membre de notre centre

7 Une structure d'accompagnement ou de soins pour jeunes

8 Un autre centre de santé mentale (institut, psychiatre, psychologue, travailleur social)

9 Un autre centre spécialisé dans les addictions

10 Un juge, une personne chargée de la probation

11 Autre: _____

## APPENDIX D

## This protocol: revision chronology

| | |
|---|---|
| 2016 December 1 | Original |
| 2017 March 3 | Approval by ethical committees added |
| 2017 August 11 | Name of O Phan added to the Paris/Sceaux MDFT therapist mentioned |
| 2017 November 2 | Administrative details (such as this table) added to conform to the SPIRIT guidelines for reporting on study protocols.<br>The term 'pilot' (pilot study) has been dropped. The enormous effort put into this study does not warrant the use of the term 'pilot'. |
| | |
| | |