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Study Protocol of the Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE), Korea, 2015–2019

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Study Protocol of the Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE), Korea, 2015–2019

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Abstract

Introduction:

In 2013, the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) proposed nine internet gaming disorder (IGD) diagnostic criteria as a condition warranting further empirical and clinical research. The aim of this study is to clarify the natural and clinical courses of IGD proposed DSM-5 in adolescents and to evaluate its risk and protective factors.

Method and analysis:

The Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE) study is an ongoing multidisciplinary, prospective, longitudinal cohort study conducted in 21 schools in Korea. Participant recruitment commenced in March 2015 with the goal of registering 3,000 adolescents. The baseline assessment included surveys on emotional, social, and environmental characteristics. A parent or guardian completed questionnaires and a structured psychiatric comorbidity diagnostic interview regarding their children. Adolescents with the Internet Game Use-Elicited Symptom Screen (IGUESS) total scores of 6 or higher were asked to participate in the clinical diagnostic interview. Two sub-cohorts of adolescents were constructed: a representative sub-cohort and a high-risk IGD sub-cohort. The representative sub-cohort comprises a randomly selected 10% of the iCURE to investigate the clinical course of IGD based on clinical diagnosis and to estimate the false negative rate. The high-risk IGD sub-cohort comprised participants meeting 3 or more of the nine IGD criteria, determined by clinical diagnostic interview, to show the clinical course of IGD. Follow-up data will be collected annually for the three years following the baseline assessments. The primary endpoint is 2-year incidence, remission, and recurrence rates of IGD. Cross-sectional and longitudinal associations between exposures and outcomes as well as mediation factors will be evaluated.

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4 Ethics and dissemination: This study is approved by the Institutional Review Board of The
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6 Catholic University of Korea. Results will be published in peer-reviewed journals. This
7
8 study's protocol is registered at clinicaltrials.gov (identifier: NCT02415322).
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11 12 13 14 15 16 17 18 19 20 **Article summary**

21 Strengths and limitations of this study

- 22
23 ● Internet gaming disorder (IGD) was assessed by using both polychotomous and
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25 dichotomous tools based on the nine DSM-5 IGD criteria. In addition, we are
26
27 conducting structured interviews using DISC-IV of the parents or guardians to assess
28
29 participant psychiatric comorbidities.
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- 32
33 ● This study is that the clinical diagnosis of IGD based on the DSM-5 is performed by
34
35 qualified mental health specialists.
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- 38
39 ● It is not a representative sample because the registration was conducted among the
40
41 schools in the specific area.
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- 44
45 ● The participants were included only 3rd-, 4th-, and 7th-grade students.
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Introduction

Internet games are popular entertainment in modern society, with a variety of people of different ages participating in gaming. Internet game play rates and sales are increasing¹.

Players choose to play games for many reasons, including fun, recreation, coping with stress, sociability, and escaping real life²⁻⁴. The gaming research literature has reported both positive and negative effects on players. Playing games promotes problem solving and visual, motor, and spatial skills, and it fosters interaction with friends⁵. Although there are several positive effects of playing games for adolescents, there can also be negative effects, such as the possibility of problematic or addictive gaming⁶. Gaming has been associated with inattention and hyperactivity, aggressive behaviors, negative emotions including depression^{7,8}, low self-esteem, social anxiety, loneliness⁹, and low psychological well-being¹⁰.

South Korea is one of the most highly digitalized societies in the world. The Internet penetration rate in South Korea exceeded 75% in 2011¹¹. More than half of people in their 50s and almost 100% of teenagers use the Internet in their daily lives¹². Korea has developed a computer industry with Internet use reaching over 50% of the population. Currently, in Korea, 25 million among 45 million citizens use the Internet, and 14.4 million homes are equipped with Internet access. In addition to home access, many people visit “PC rooms”, a type of gaming center with a broad-band Internet network that is equipped with the best performance computers in Korea. PC rooms became popular following the release of the PC game StarCraft in 1998, with an estimated 25,000 PC rooms nationwide in 2014. ‘PC rooms’ have no any age restrictions on accessibility, and many adolescents often play online games¹³. A 2010 nation-wide survey regarding Internet addiction showed that 8.0% of the Korean population and 12.4% of adolescents were addicted to Internet use, as assessed via the self-administered K-scale¹². This prevalence is a little higher than has been found in other countries, such as Singapore (8.7%)¹⁴, the Netherlands (6.8%)¹⁵, the US (8.5%)¹⁶, and

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4 China (10.8%)¹⁷. The higher prevalence in Korea could be expected, given that it is a country
5
6 with such broad and easy access. Although the number of Internet game users has increased
7
8 dramatically over the last decade, the phenomenon of Internet gaming addiction is not yet
9
10 well understood, and research on its etiology and natural history is still in its infancy [2].
11
12 Studies have used various tools to estimate the prevalence of -Internet gaming disorder (IGD),
13
14 but the lack of common diagnostic criteria for IGD has created difficulties in comparing
15
16 studies.
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19 In May 2013, IGD was included in Section III of the DSM-5 as a condition warranting
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21 further study¹⁸. This marked the first occasion of IGD being formally recognized as a mental
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23 health disorder. Even though the classification and rationale for including this condition as a
24
25 mental health disorder have been controversial, the suggested IGD classification criteria have
26
27 paved the way for measuring IGD in a consistent manner. These suggestions enable more
28
29 direct comparisons of findings and may be used to eventually reach a consensus on the status
30
31 of the disorder¹⁹. The DSM-5 proposes nine criteria for IGD, and it states explicitly that the
32
33 specific criteria and the threshold for diagnosis require systematic investigation and empirical
34
35 validation before their wide-scale adoption. The proposed criteria apply only to Internet
36
37 gaming, and not general Internet use, which can differ in terms of presenting symptoms,
38
39 etiology, comorbidities, course, and treatment. Empirical data are required to ascertain the
40
41 extent to which these criteria apply to various populations and to aid diagnosis. To this end,
42
43 we registered and began a prospective school-based cohort study of adolescents to provide
44
45 evidence regarding the IGD diagnostic criteria by clarifying the characteristics of IGD's
46
47 natural history. Given the broad discussion of a replicability "crisis" in many sciences, it is
48
49 valuable to document *a priori* our research methods, goals, and planned approach.
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57 Aims
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4 The aim of the study is to clarify the natural and clinical courses of IGD based on the DSM-5
5 diagnostic criteria, to provide evidence for empirical validation of the suggested IGD
6 diagnostic criteria, and to further evaluate the etiological risk and predictive factors in
7 adolescents.
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14 **Methods**

15 **Study design and setting**

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17 The Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence
18 (iCURE) study is a multidisciplinary, prospective, longitudinal cohort study of 3,000
19 adolescents, conducted in Korea, with 4 waves of annual data collection currently planned.
20 The study is being conducted in Seoul and Uijeongbu, Gyeonggi Province, with 3rd-, 4th-, and
21 7th-grade students in 6 primary schools and 19 secondary schools participating. Participation
22 requires consent from the participants as well as written parental consent following
23 explanation of the nature of the principles of research, including confidentiality and the
24 freedom of choice to participate. The study was fully reviewed and approved by the
25 Institutional Review Board of The Catholic University of Korea (MC140NM10085) and was
26 conducted in accordance with the Declaration of Helsinki.
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44 **Pretest and pilot test of methods**

45 We validated the feasibility of the study before beginning data collection by performing a
46 pretest and a pilot test. For the pretest, we recruited a convenience sample of 25 3rd- and 4th-
47 grade students to test the understandability of the questionnaires for this age group of students.
48 We performed a pilot test to verify that the overall survey system worked well, with
49 participants composed of one school class of 35 students. They completed all baseline
50 measures which were recruited outside of the sampling frame.
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Recruitment

Participant recruitment commenced in March 2015. Recruitment took place at the school level. We sent official letters to all primary and secondary schools in three educational districts to invite their participation. After school principles provided consent for their schools to participate, the parents or guardians were contacted to obtain consent for their children to participate in the study. A total of 21 schools (6 elementary and 19 secondary) participated in the study, out of 258 schools (163 elementary and 95 secondary) in the three districts. In order to encourage participation in this research, the research team members visited the 21 participating schools to provide a seminar that presented the aims of the study and provided additional information about the research project to teachers and parents. The final enrollment is expected to be 3,000 adolescents. Three regional hospitals were designated in the three areas where the participating schools are located to provide treatment options for adolescents experiencing IGD.

Inclusion and exclusion criteria

The inclusion criteria were that the participants were 3rd-, 4th-, or 7th-grade students at baseline. We required that each student participant had a parent or guardian who also participated in the study. The exclusion criteria included lack of competence in the Korean language by the parent or guardian and intellectual disability of the adolescent.

Data collection

The participants completed questionnaires at baseline and will again annually for the following three years. The baseline assessments started in May 2015. We are collecting data from multiple informants, including students' self-report questionnaires, clinical diagnostic

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4 interviews of the students, parents' or guardians' self-report questionnaires, and structured
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6 clinical interviews of the parents or guardians regarding any psychiatric comorbidity in their
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8 children.
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10 11 12 13 Follow-up and retention strategy

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15 In an effort to maintain contact with iCURE study participants, we will send individual
16
17 reports annually via registered mail, and we will periodically send text messages about
18
19 general contents via cell phone to the participants. Once a year, we will send each
20
21 participant's survey results to their parents via registered mail, which will be called a "mental
22
23 health signal." This will include the mental health status regarding symptoms of Internet
24
25 game addiction, depression, anxiety, and ADHD, marked as red, yellow, and green traffic
26
27 signals, indicating symptom severity as assessed by both the self-report survey and the
28
29 clinical diagnosis. We will also provide referrals for treatment availability.
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33 During this study, we are operating a 24-hour counseling helpline for the parents and
34
35 guardians. A clinical psychologist with more than 10 years of clinical experience specializing
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37 in children and adolescents is conducting telephone consultations. This telephone counseling
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39 is free and anonymous, providing parents with general counseling about their children, as
40
41 well as specific counseling regarding gaming addiction.
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46 47 *Student self-report questionnaires*

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49 Student data collection is conducted at the schools during school hours. The 7th-grade students
50
51 complete questionnaires using a web-based self-administration method. The 3rd- and 4th-grade
52
53 students complete the questionnaires in a class setting; a research assistant reads the questions
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55 aloud, following a standard script, to aid comprehension and diminish time demands. In later
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57 waves, all students will complete the questionnaires on their own, with a supervising research
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4 assistant available to answer questions. During the baseline assessment, the questionnaires
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6 took approximately 90–120 minutes to complete; later waves will take approximately 45–80
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8 minutes.
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10 The student data collection at later waves will also be conducted at the schools during school
11
12 hours. For students who transfer to other schools, arrangements will be made to complete the
13
14 follow-up questionnaires, either by visiting their homes or via website access.
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17 18 19 *Interviewing parents*

20
21 At baseline, each parent or guardian completed a questionnaire and the Diagnostic Interview
22
23 Schedule for Children, Version 4 (DISC-IV). The DISC-IV is a highly structured diagnostic
24
25 interview used to assess psychiatric disorders in children and adolescents. We are including 7
26
27 of the 34 diagnostic assessments: generalized anxiety disorder, separation anxiety, obsessive-
28
29 compulsive disorder, major depression disorder, attention deficit disorder and attention deficit
30
31 hyperactive disorder (ADD/ADHD), oppositional defiant disorder, and conduct disorder.
32
33 The DISC-IV was administered by trained interviewers at the participants' homes or at a
34
35 private space at the school, based on the participant's preference. The parent questionnaire
36
37 contained demographic questions and took 20 to 30 minutes to complete, and the DISC-IV
38
39 took 40 to 90 minutes. Parent or guardian survey is conducting only at baseline.
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46 *Second-stage clinical diagnosis by mental health professionals*

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48 The clinical diagnostic interviews for IGD were conducted face-to-face by five psychiatrists
49
50 and four Master's degree-level clinical psychologists with at least five years of training and
51
52 clinical experience. The interviews assessed participants based on the nine DSM-5 IGD
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54 criteria, in accordance with the international consensus for IGD represented in the DSM-5¹⁹.
55
56 Diagnoses were based on clinically significant functional impairments that substantially
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4 derived from gaming and not from any other psychiatric illnesses. Any psychiatric
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6 comorbidities were also thoroughly evaluated by the psychiatrists using the semi-structured
7
8 tool of the Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime
9
10 Version-Korean version (K-SADS-PL), which has been previously validated in Korean²⁰.
11
12 Global functioning was assessed using the Children's Global Assessment Scale (GAS), based
13
14 on the child's worst level of emotional and behavioral functioning in the past three months.
15
16 The criterion for a second-stage clinical diagnosis is an Internet Game Use-Elicited Symptom
17
18 Screen (IGUESS) total score of 6 or higher, either at baseline or at the follow-up waves.
19
20 Additionally, random selection of 10% of the full cohort, stratified by the school, completed
21
22 the clinical diagnostic interviews at baseline and the further follow-up waves. Anyone who
23
24 responds insincerely with marking all of the same numbers to the IGUESS at every wave will
25
26 be excluded to rule out false negatives. Anyone who reports a suicidal experience during the
27
28 past year at any wave will be given diagnostic interviews. The clinical diagnostic interviews
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30 are being conducted one week after completion of the baseline study. The interviews are
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32 being conducted confidentially in private spaces at the participants' schools.
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39 *Sub-cohorts*

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41 Two sub-cohorts have been constructed. A representative sub-cohort consists of a randomly
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43 selected 10% of adolescents in the cohort. They will participate in the clinical diagnostic
44
45 interview every year to estimate the false negative rate and to evaluate the clinical course of
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47 DSM-5–defined IGD based on clinical diagnosis. Additionally, a high-risk IGD sub-cohort is
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49 comprised of those meeting 3 or more of the 9 IGD criteria, as determined by the clinical
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51 diagnostic interview at baseline and at each follow-up wave. The interviews will be
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53 conducted annually for 3 years to observe the clinical history, remission, and recurrence rates.
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Measurement

The measurements using i-CURE are presented in Table 1.

Demographic information

Demographic characteristics were assessed at baseline. Sex, date of birth, family composition, and number of siblings were obtained from the student assessment, and parental education level, socio-economic status, parental marital status, parental education level, and parental job were obtained from the parent or guardian assessments.

Internet, gaming, and smartphone use

Comprehensive assessments of participants' Internet, gaming, and smartphone usage were performed, including questions regarding the first time of exposure, the average daily time spent online, and gaming-related questions, such as online gaming type preference and weekly playing time. We classified online games as role-playing games, shooter games, simulation games, arcade games, and unknown.

Regulated usage of smartphones or games

We assess school policies on possession and usage of smartphones and domestic regulations of smartphone or game time.

Internet Addiction Test (IAT)

Young's IAT consists of 20 items rated on a 5-point Likert scale from *rarely* (1) to *always* (5), with higher scores indicating more severe Internet addiction²¹.

Korean Scale for Internet Addiction (K-Scale)

To assess Internet addiction, we use the K-Scale-short form for adolescents, which were developed in Korea. It is comprised of 20 items rated on a 4-point Likert scale, from 1 (*not at all*) to 4 (*always*)²².

Internet Game Use-Elicited Symptom Screen (IGUESS)

This instrument was created based on the nine DSM-5 IGD criteria. Students are instructed to

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4 respond based on their gaming behavior within the last 12 months, with each item rated on a
5
6 4-point scale: 1=*strongly disagree*, 2=*somewhat disagree*, 3=*somewhat agree*, 4=*strongly*
7
8 *agree*).

10 *Self-reported version of structured clinical interview for Internet Gaming Disorder (SR-IGD)*

11
12 We use the SR-IGD to assess IGD with respect to occurrences over the past 6 months. The
13
14 assessment uses yes-or-no questions²³.

17 *Smartphone Addiction Scale (SAS-SV)*

18
19 We assessed smartphone addiction using the short version of the Smartphone Addiction Scale
20
21 (SAS-SV). The SAS-SV addresses the following 5 content areas with respect to the previous
22
23 year: (1) daily-life disturbance, (2) withdrawal, (3) cyberspace-oriented relationship, (4)
24
25 overuse, and (5) tolerance. It contains 10 items rated on a dimensional scale (1=*strongly*
26
27 *disagree* to 6=*strongly agree*). The total scores range from 10 to 60, with the higher scores
28
29 indicating greater degrees of smartphone addiction²⁴.

32 *Children's Depression Inventory (CDI)*

33
34 The Children's Depression Inventory (CDI) is a 27-item, self-rated, symptom-oriented scale
35
36 suitable for youths aged 7 to 17 years. It assesses cognitive, affective, somatic, and behavioral
37
38 symptoms, with items scored from 0 to 2, where 0 means *the symptom is not present*, 1 means
39
40 *the symptom is present and mild*, and 2 means *the symptom is present and marked*²⁵.

43 *Trait Anxiety Inventory for Children (TAIC)*

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45 To examine trait anxiety, we used the Korean translation²⁶ of the Trait Anxiety Inventory for
46
47 Children (TAIC), which is part of the State-Trait Anxiety Inventory for Children (STAIC)
48
49 developed by Spielberger and colleagues (1973). The Korean TAIC is a 20-item inventory
50
51 that asks respondents to indicate how frequently, on a 3-point scale (1=*almost never* to
52
53 3=*almost always*), they feel worried, bothered, or nervous²⁷..

56 *Korean version of the ADHD Rating Scale (K-ARS)*

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4 The Korean version of the ADHD Rating Scale (K-ARS) was used to assess ADHD which
5 was originally developed by DuPaul²⁸. The K-ARS is a scale for ADHD symptom severity
6 composed of 18 items (9 items for inattention and 9 items for hyperactivity) scored from as 0
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The Korean version of the ADHD Rating Scale (K-ARS) was used to assess ADHD which was originally developed by DuPaul²⁸. The K-ARS is a scale for ADHD symptom severity composed of 18 items (9 items for inattention and 9 items for hyperactivity) scored from as 0 (never or rarely) to 3 (very often)²⁹.

Diagnostic Interview Schedule for Children, Version IV (DISC-IV)

In the current study, the DISC-IV was administered by a trained interviewer. The DISC-IV is comprised of six domains of possible impairment present during a “time in the last year when symptoms caused the most problems.” These domains are (1) getting along with parent caretakers, (2) participating in family activities, (3) participating in peer activities, (4) academic/occupational functioning, (5) relationships with teachers, and (6) distress attributable to symptoms. Each set of questions has a 2-part structure, the first determining whether impairment is present, and the second measuring severity or frequency. We selected an introductory module that includes demographic information (age, grade, names and ages of siblings, and identification of caretakers and attachment figures). The remainder of the interview is organized into 3 modules, each containing related diagnoses (anxiety, mood, and disruptive disorders)³⁰.

Presence of suicidal ideation, suicide plans, and suicide attempts

The presence of suicidal ideation, suicide plans, and suicide attempts is determined using the following direct questions derived from the Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I). Participants are asked whether they had seriously considered committing suicide, made a plan to commit suicide, or attempted suicide during the past year. The presence or absence of suicide ideation, plans, and attempts is based on the subject response (yes or no)³¹

Patient Health Questionnaire (PHQ-9)

The PHQ-9 is a multipurpose instrument that assists in screening, diagnosing, and monitoring

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4 depression severity. It incorporates the DSM-IV depression diagnostic criteria with other
5
6 leading major depressive symptoms into a brief nine-item, self-report tool. Respondents rate
7
8 the frequency of the symptoms over the last 2 weeks on a 4-point rating scale (*not at all* = 0;
9
10 *several days* = 1; *more than half of the days* = 2; *nearly every day* = 3) ³².

11 12 *Rosenberg's Self-Esteem Scale*

13
14 Rosenberg's Self-Esteem Scale has 10 items, each rated on a 5-point Likert scale, ranging
15
16 from 1 (*strongly disagree*) to 5 (*strongly agree*). The total score ranges from 10 to 50 ³³.

17 18 *Self-Control Scale*

19
20 Self-Control Scale is defined by Gottfredson and Hirschi (1990) ³⁴. The 20-item scale is
21
22 divided into two self-control constructs: immediate and delayed satisfaction. Each item is
23
24 rated on a 4-point scale: (4) *strongly agree*, (3) *agree somewhat*, (2) *disagree somewhat*, and
25
26 (1) *strongly disagree*. Higher scores indicate lower self-control.
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29 30 *Aggression Questionnaire (AQ)*

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32 The Buss-Perry Aggression Questionnaire is a 29-item scale that measure four aspects of
33
34 human aggression and hostile personality. Participants rate each item using a 5-point Likert
35
36 scale from 1 (*uncharacteristic of me*) to 5 (*very characteristic of me*)³⁵.

37 38 *Social Support Appraisals Scale: Child's Subjective Appraisal of Family, Peer, and Teacher* 39 40 *Support (SSAS)*

41
42 We use the Social Support Appraisals Scale: Child's Subjective Appraisal of Family, Peer,
43
44 and Teacher Support (SSAS) to address the adolescent participants' perceived support. It is a
45
46 41-item self-report instrument developed by Dubow et al. (1989) ³⁶. Items are rated on a 5-
47
48 point Likert scale, from 1 (*never*) to 5 (*always*).
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51 52 *Parent-Adolescent Communication Inventory (PACI)*

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54 The Parent-Adolescent Communication Inventory (PACI) is a 40-item inventory used to
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56 assess communication in the parent–adolescent relationship. There are two forms of the
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4 inventory, one for parents and the other for adolescents. Scores range from 0 to 120, with
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6 higher scores reflecting a greater degree of parent-adolescent communication ³⁷.
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8 *The Children's Perception of Interparental Conflict Scale (CPIC)*

9
10 The CPIC uses a multiple-choice format with three possible responses: *true*, *sort of true*, and
11
12 *false*. Items are scored from 1 to 3, with 3 reflecting more negative forms of conflict and their
13
14 appraisal ³⁸.
15

16 *Revised Inventory of Parent and Peer Attachment (IPPA_R)*

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18 The original IPPA was developed by Armsden and Greenberg (1987) to assess adolescents'
19
20 perceptions of the positive and negative affective and cognitive dimensions of relationships
21
22 with their parents and close friends. In particular, the inventory examines how well these
23
24 figures serve as sources of psychological security. Three broad dimensions are assessed:
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26 degree of mutual trust, quality of communication, and alienation. Participants are asked to
27
28 rate each of the items on a 5-point Likert-scale from 1 (*never true*) to 5 (*always true*) ³⁹.
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32 *Physical and mental health status*

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34 We assess physical pain experiences, such as in the hand, wrist, shoulder, or neck; dry eyes;
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36 drinking and smoking habits during the past year; histories of physical illness, including
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38 rheumatoid arthritis, lupus, diabetes mellitus; and psychiatric illness, including depression,
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40 anxiety disorders, and ADHD. We also ask about sleep hours during the week and during
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42 weekends.
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46 *Sample size estimation*

47
48 We calculated the study sample size required to investigate whether overuse of Internet
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50 gaming is a risk factor of IGD presence at the 2-year follow up. For a 15% prevalence of
51
52 exposure to 3 or more hours per day of Internet gaming, a 5% incidence of IGD at the 2-year
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54 follow-up period, a relative risk of this risk factor for IGD of 2 (RR=2.0), and setting α at
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4 0.05 and β at 0.20 (power of 0.80), a sample size of 2,559 is required. Considering a dropout
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6 rate of 14%, the required sample size is estimated to be almost 3,000. We expect there will be
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8 150 adolescents at high-risk for IGD (meeting 3 or more of the 9 DSM-5 IGD criteria) among
9
10 the 3,000 participants at baseline, and we estimate that 75 new IGD cases will be found at the
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12 2-year follow-up⁴⁰.

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17 Strategies to minimize error and bias

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19 *Online assessment system*

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21 The participants log onto the study's website with unique authentication codes provided,
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23 where they complete the online questionnaires. We use a branched algorithmic structure to
24
25 enhance the confidentiality and accuracy of responses and to reduce the risk of exposing
26
27 sensitive information.

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30 *Training of the interviewers*

31
32 To administer the parent-guardian surveys, we recruited psychologists and nurses with
33
34 Bachelor's or Master's degrees, and the research team provided them with training that
35
36 included information on Internet gaming addiction and communication skills, through a 2-day
37
38 (16-hour) training workshop. In addition to administering the surveys, the interviewers
39
40 reported on the status of the data collection and any problems and issues arising during the
41
42 interviews, at mandatory weekly meetings.

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45 Prior to the diagnostic interviews and twice each year, all psychiatrists and clinical
46
47 psychologists attend a seminar about IGD diagnosis to increase inter-rater reliability and
48
49 diagnostic agreement. In the seminar, we review recent papers on IGD diagnosis and provide
50
51 mock cases in a video to enhance diagnostic concordance. Also, at the end of each day of
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53 diagnostic interviews, all psychiatrists and clinical psychologists who participate in the
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55 clinical diagnosis attend a case conference to discuss any ambiguous diagnoses and make
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4 final determinations.
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8 9 Statistical analyses plan

10 We will calculate the 2-year incidence, remission, and recurrence rates of IGD, with 95%
11 confidence intervals. We will investigate the cross-sectional and longitudinal associations
12 between exposures and outcomes using a logistic or linear regression model or a generalized
13 linear model, as appropriate. Models will include exposures to games, such as time spent
14 playing games, types of Internet games, and gaming-related activities, with IGD as the
15 outcome variable and covariates including socio-demographic, personal, social, and
16 environmental factors. Moderation tests will examine for differences in associations and
17 mediation tests will assess indirect effects based on socio-demographic, personal, social, and
18 environmental factors.
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33 **Ethics and dissemination**

34 All procedures performed in studies involving human participants were in accordance with
35 the ethical standards of the Institutional Review Board of The Catholic University of Korea
36 (approval number: MC140NM10085) and with the 1964 Helsinki declaration and its later
37 amendments or comparable ethical standards. Written consent was received from all
38 participants and from one of the participants' parents or caregivers following an explanation
39 of the study, including confidentiality and freedom of choice to participate. All results will be
40 published in relevant peer-reviewed international scientific journals and presented at conferences, nationally and
41 internationally.
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54 **Discussion**

55 A major strength of this study is that it is conducted in a county with a particularly high
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4 burden of IGD in adolescents. Korea has a high likelihood of exposure to games because
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6 Korea plays a leading role in the development of the game industry and is one of the most
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8 highly digitalized societies in the world. It provides a high-access environment for Internet
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10 gaming, including PC rooms, which have broad-band Internet networks and are equipped
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12 with the best performance computers in Korea. This makes Korea an optimal place to
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14 perform a cohort study to characterize IGD.

15
16 We are screening 3rd-, 4th-, and 7th-grade students for IGD using both polychotomous and
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18 dichotomous tools based on the nine DSM-5 IGD criteria. In addition, we are conducting
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20 structured interviews using DISC-IV of the parents or guardians to assess participant
21
22 psychiatric comorbidities. Because the participants are early adolescents, we obtained their
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24 mental health status through their parents or guardians. Self-reports can include false or
25
26 insincere reports, making evaluation of the IGD risk factors less accurate. To reduce this
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28 effect, we have added a reverse scale to each self-report questionnaire.

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30 Another strength of this study is that the clinical diagnosis of IGD based on the DSM-5 is
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32 performed by qualified mental health specialists. Most prior studies have not been able to
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34 also get a true clinical diagnosis along with the screening tool scores, so this study will
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36 provide needed validity data. Participants included those considered positive for IGD, defined
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38 as scores of 6 or higher on IGUESS, as well as a reference group of a random selection of 10%
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40 of the participants. We have constructed two sub-cohorts from those who have participated in
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42 the clinical diagnosis: a representative and a high-risk cohort. The representative sub-cohort
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44 consists of 10% randomly selected adolescents from the full cohort. They participate in the
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46 clinical diagnostic interview every year in order to estimate the false negative rate and to
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48 evaluate the clinical course of IGD, observed via the diagnostic interviews. The high-risk
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50 sub-cohort is comprised of participants meeting 3 or more of the 9 IGD criteria, based on the
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52 clinical diagnostic interviews at baseline and each follow-up wave. The high-risk sub-cohort
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4 is similar to a dynamic cohort. The suggested diagnostic criteria of IGD in DSM-5 is to meet
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6 5 or more of the 9 IGD criteria; however, we plan to follow those adolescent participants
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8 meeting 3 or more clinical diagnostic interview in any year in order to investigate the course
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10 of IGD at syndromal and subsyndromal levels.

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12 This study aims to clarify the natural and clinical courses of IGD based on the DSM-5
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14 suggested diagnostic criteria in order to empirical validate the criteria and to evaluate the risk
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16 and predictive factors in adolescents based on the IGD diagnostic criteria. This study will
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18 contribute to establishing standardized IGD diagnostic criteria and to providing scientific
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20 evidence regarding the proposed DSM-5 IGD diagnostic criteria.
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28 **Keywords:**

29 Internet gaming disorder, adolescents, cohort, protocol
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32 **Lists of Abbreviations**

33 Aggression Questionnaire (AQ)
34 Attention Deficit Hyperactivity Disorder (ADHD)
35 Children's Depression Inventory (CDI)
36 Children's Perception of Inter-parental Conflict Scale (CPIC)
37 Diagnostic and Statistical Manual of Mental Disorders 5th version (DSM-5)
38 Diagnostic Interview Schedule for Children, Version IV (DISC-IV)
39 Global assessment scale (GAS)
40 International Classification of Diseases 10th version (ICD-10)
41 International Classification of Diseases 11th version (ICD-11)
42 Internet Game Use-Elicited Symptom Screen (IGUESS)
43 Internet gaming disorder (IGD)
44 Internet user Cohort for Unbiased Recognition of gaming disorder in Early adolescents
45 (iCURE)
46 Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version-
47 Korean version (K-SADS-PL)
48 Korean version of the ADHD Rating Scale (K-ARS)
49 Parent-Adolescent Communication Inventory (PACI)
50 Parent-Adolescent Communication Inventory (PACI)
51 Parenting attitude test (PAT)
52 Patient Health Questionnaire (PHQ-9)
53 Post-traumatic stress disorder (PTSD)
54 Revised Inventory of Parent and Peer Attachment (IPPA-R)
55 Smartphone Addiction Scale (SAS-SV)
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4 Social Support Appraisal Scale (SSAS)
5 Standard Patients Evaluation of Eye Dryness Questionnaire (SPEED)
6 Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)
7 Self-reported version of structured clinical interview for Internet Gaming Disorder (SR-IGD)
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10
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13 Project, Ministry of Health and Welfare, Republic of Korea (HM14C2603). The Ministry of
14 Health and Welfare had no further role in areas of study design, collection, analysis, and
15 interpretation of data, report writing, or in the decision to submit the paper for publication.
16

17 **Availability of data and materials**

18 Not applicable. This protocol was not included any participants data.
19

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21 **Authors' contribution:**

22 HJ conducted the analyses and led the writing of the manuscript. HWY guided and
23 supervised the writing of the manuscript. HWY, HJ, and SJ developed and proposed the basic
24 idea of the study. HWY, HJ, SJ, EK, HS and HH contributed to conducting the study. SL, HL,
25 YK, SB, and JC conducted diagnostic interviews. BK guided to performance DISC
26 assessment. DAG advised to construct study design. DAG and MNP reviewed scientific and
27 proof reading of the manuscript. All authors contributed editorial comments on the
28 manuscript.
29

30
31 **Conflict of interest:**

32 The authors declare no conflicts of interest with respect to the content of the manuscript..
33

34 **Consent for publication**

35 Not applicable.
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Table 1. Measurement tools in each wave

Categories	Measures	Source	Wave			
			T1	T2	T3	T4
Exposure	Exposure time to internet, smart phone, and online game	student/parents	√	√	√	√
	Internet, smart phone, and online game using behaviors	Student	√	√	√	√
Diagnosis	Young scale	Student	√			
	K-scale	Student	√			
	IGUESS	Student	√	√	√	√
	IGDS	Student	√		√	√
	SAS-SV	Student	√	√	√	√
Psychiatric commorbidity	Depression (CDI)	Student	√	√	√	√
	Anxiety (TAIC)	Student	√	√	√	√
	K-ARS	Parents	√			
	DISC-IV	Parents	√			
	Sociality	Student	√	√	√	√
	PHQ-9	Parents	√			
	Personal	Self-esteem scale	student	√		
	Gottfredson' self-control	student	√			
	Aggression Questionnaire	student	√	√	√	√
	Demographic information	student/parents	√			
	Academic achievement	Parents	√			
Environmental	School policy on having smart phone use in school	student	√	√	√	√
	PACI	student	√			
	Marriage satisfaction	Parents	√			
	PAT	student/parents	√			
	CPIC	student	√			
	IPPA-R	student	√			
	Perceived Parenting Competence	Parents	√			
Social	Online gaming rule in home	Parents	√	√	√	√
	Social network	Student	√			
	Bullying scale	student	√			
	SSAS	student	√			
Health consequence	Physical health	student/parents	√			
	Mental health	students	√			

PACI: Parent-Adolescent Communication Inventory; SPEED: Standard Patients Evaluation of Eye Dryness Questionnaire; IPPA-R: Revised Inventory of Parent and Peer Attachment PACI: Parent-Adolescent Communication Inventory; AQ: Aggression Questionnaire; PAT: Parenting attitude test; CPIC: The Children's Perception of Inter-parental Conflict Scale; SSAS: Social Support Appraisal Scale

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Study Protocol of the Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE), Korea, 2015–2019

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Study Protocol of the Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE), Korea, 2015–2019

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Abstract

Introduction:

In 2013, the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5) proposed nine internet gaming disorder (IGD) diagnostic criteria as a condition warranting further empirical and clinical research. The aim of this study is to clarify the natural and clinical courses of IGD proposed DSM-5 in adolescents and to evaluate its risk and protective factors.

Method and analysis:

The Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence (iCURE) study is an ongoing multidisciplinary, prospective, longitudinal cohort study conducted in 21 schools in Korea. Participant recruitment commenced in March 2015 with the goal of registering 3,000 adolescents. The baseline assessment included surveys on emotional, social, and environmental characteristics. A parent or guardian completed questionnaires and a structured psychiatric comorbidity diagnostic interview regarding their children. Adolescents with the Internet Game Use-Elicited Symptom Screen (IGUESS) total scores of 6 or higher were asked to participate in the clinical diagnostic interview. Two sub-cohorts of adolescents were constructed: a representative sub-cohort and a clinical evaluation sub-cohort. The representative sub-cohort comprises a randomly selected 10% of the iCURE to investigate the clinical course of IGD based on clinical diagnosis and to estimate the false negative rate. The clinical evaluation sub-cohort comprised participants meeting three or more of the nine IGD criteria, determined by clinical diagnostic interview, to show the clinical course of IGD. Follow-up data will be collected annually for the three years following the baseline assessments. The primary endpoint is two-year incidence, remission, and recurrence rates of IGD. Cross-sectional and longitudinal associations between exposures and outcomes as well as mediation factors will be evaluated.

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4 Ethics and dissemination: This study is approved by the Institutional Review Board of The
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6 Catholic University of Korea. Results will be published in peer-reviewed journals. This
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8 study's protocol is registered at clinicaltrials.gov (identifier: NCT02415322).
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20 **Article summary**

21 Strengths and limitations of this study

- 22 ● Internet gaming disorder (IGD) was assessed by using both polychotomous and
23 dichotomous tools based on the nine DSM-5 IGD criteria. In addition, we are
24 conducting structured interviews using DISC-IV of the parents or guardians to assess
25 participant psychiatric comorbidities.
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- 28 ● This study is that the clinical diagnosis of IGD based on the DSM-5 is performed by
29 qualified mental health specialists.
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- 32 ● It is not a representative sample because the registration was conducted among the
33 schools in the specific area.
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- 36 ● The participants were included only 3rd-, 4th-, and 7th-grade students.
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Introduction

Internet games are popular entertainment in modern society, with a variety of people of different ages participating in gaming. Internet game play rates and sales are increasing¹.

Players choose to play games for many reasons, including fun, recreation, coping with stress, sociability, and escaping real life²⁻⁴. The gaming research literature has reported both positive and negative effects on players. Playing games promotes problem solving and visual, motor, and spatial skills, and it fosters interaction with friends⁵. Although there are several positive effects of playing games for adolescents, there can also be negative effects, such as the possibility of problematic or addictive gaming⁶. Gaming has been associated with inattention and hyperactivity, aggressive behaviors, negative emotions including depression^{7,8}, low self-esteem, social anxiety, loneliness⁹, and low psychological well-being¹⁰.

South Korea is one of the most highly digitalized societies in the world. The Internet penetration rate in South Korea exceeded 75% in 2011¹¹. More than half of people in their 50s and almost 100% of teenagers use the Internet in their daily lives¹². Korea has developed a computer industry with Internet use reaching over 50% of the population. Currently, in Korea, 25 million among 45 million citizens use the Internet, and 14.4 million homes are equipped with Internet access. In addition to home access, many people visit “PC rooms”, a type of gaming center with a broad-band Internet network that is equipped with the best performance computers in Korea. PC rooms became popular following the release of the PC game StarCraft in 1998, with an estimated 25,000 PC rooms nationwide in 2014. ‘PC rooms’ have no any age restrictions on accessibility, and many adolescents often play online games¹³.

A 2010 nation-wide survey regarding Internet addiction showed that 8.0% of the Korean population and 12.4% of adolescents were addicted to Internet use, as assessed via the self-administered K-scale¹². This prevalence is a little higher than has been found in other countries, such as Singapore (8.7%)¹⁴, the Netherlands (6.8%)¹⁵, the US (8.5%)¹⁶, and

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4 China (10.8%)¹⁷. The higher prevalence in Korea could be expected, given that it is a country
5
6 with such broad and easy access. Although the number of Internet game users has increased
7
8 dramatically over the last decade, the phenomenon of Internet gaming addiction is not yet
9
10 well understood, and research on its etiology and natural history is still in its infancy. Studies
11
12 have used various tools to estimate the prevalence of Internet gaming disorder (IGD), but the
13
14 lack of common diagnostic criteria for IGD has created difficulties in comparing studies.

15
16
17 In May 2013, IGD was included in Section III of the DSM-5 as a condition warranting
18
19 further study¹⁸. This marked the first occasion of IGD being formally recognized as a mental
20
21 health disorder and suggested IGD classification criteria have paved the way for measuring
22
23 IGD in a consistent manner. These suggestions enable more direct comparisons of findings
24
25 and may be used to eventually reach a consensus on the status of the disorder¹⁹. The DSM-5
26
27 proposes nine criteria for IGD, and it states explicitly that the specific criteria and the
28
29 threshold for diagnosis require systematic investigation and empirical validation before their
30
31 wide-scale adoption. The proposed criteria apply only to Internet gaming, and not general
32
33 Internet use, which can differ in terms of presenting symptoms, etiology, comorbidities,
34
35 course, and treatment. Empirical data are required to ascertain the extent to which these
36
37 criteria apply to various populations and to aid diagnosis.

38
39
40
41 However, the classification and rationale for DSM-5 IGD as a mental health disorder have
42
43 been controversial²⁰. A previous study ~~was~~ proposed the possibilities that gaming behavior
44
45 can be common behavior or leisure activity. Excessive involvement on gaming per se, ~~that~~
46
47 might reflect engagement, passion, or coping²¹. Excessive behaviors on gaming can be
48
49 transient for many adolescents and we will look into whether excessive behavior on gaming
50
51 is episodic or steady through the longitudinal observation. It is also argued that several IGD
52
53 criteria such as withdrawal and tolerance are often inappropriate to be put into the
54
55 conceptualization of behavioral addiction and difficult to apply convincingly and measure in
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4 relation to behaviors²². In addition, a previous study did not support the hypothesis that the
5
6 nine DSM-5 IGD criteria had the same validity for the diagnosis²³. To this end, we registered
7
8 and began a prospective school-based cohort study of adolescents to provide evidence
9
10 regarding the IGD diagnostic criteria by clarifying the characteristics of IGD's natural history.
11
12 Given the broad discussion of a replicability "crisis" in many sciences, it is valuable to
13
14 document *a priori* our research methods, goals, and planned approach.
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20 Aims

21 The aim of the study is to clarify the natural and clinical courses of IGD based on the DSM-5
22
23 diagnostic criteria, to provide evidence for empirical validation of the suggested IGD
24
25 diagnostic criteria, and to further evaluate the etiological risk and predictive factors in
26
27 adolescents.
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33 Methods

34 Study design and setting

35
36 The Internet user Cohort for Unbiased Recognition of gaming disorder in Early Adolescence
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38 (iCURE) study is a multidisciplinary, prospective, longitudinal cohort study of 3,000
39
40 adolescents, conducted in Korea, with 4 waves of annual data collection currently planned.
41
42 The study is being conducted in Seoul and Uijeongbu, Gyeonggi Province, with 3rd-, 4th-, and
43
44 7th-grade students in 6 primary schools and 19 secondary schools participating. Participation
45
46 requires consent from the participants as well as written parental consent following
47
48 explanation of the nature of the principles of research, including confidentiality and the
49
50 freedom of choice to participate. The study was fully reviewed and approved by the
51
52 Institutional Review Board of The Catholic University of Korea (MC140NM10085) and was
53
54 conducted in accordance with the Declaration of Helsinki.
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Pretest and pilot test of methods

We validated the feasibility of the study before beginning data collection by performing a pretest and a pilot test. For the pretest, we recruited a convenience sample of 25 3rd- and 4th-grade students to test the understandability of the questionnaires for this age group of students.

We performed a pilot test to verify that the overall survey system worked well, with participants composed of one school class of 35 students. They completed all baseline measures which were recruited outside of the sampling frame.

Recruitment

Participant recruitment commenced in March 2015. Recruitment took place at the school level. We sent official letters to all primary and secondary schools in three educational districts to invite their participation. After school principles provided consent for their schools to participate, the parents or guardians were contacted to obtain consent for their children to participate in the study. A total of 21 schools (6 elementary and 19 secondary) participated in the study, out of 258 schools (163 elementary and 95 secondary) in the three districts. In order to encourage participation in this research, the research team members visited the 21 participating schools to provide a seminar that presented the aims of the study and provided additional information about the research project to teachers and parents. The final enrollment is expected to be 3,000 adolescents. Three regional hospitals were designated in the three areas where the participating schools are located to provide treatment options for adolescents experiencing IGD.

Inclusion and exclusion criteria

The inclusion criteria were that the participants were 3rd-, 4th-, or 7th-grade students at

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2
3
4 baseline. We required that each student participant had a parent or guardian who also
5
6 participated in the study. The exclusion criteria included lack of competence in the Korean
7
8 language by the parent or guardian and intellectual disability of the adolescent.
9

10 11 12 Data collection

13
14 The participants completed questionnaires at baseline and will again annually for the
15
16 following three years. The baseline assessments started in May 2015. We are collecting data
17
18 from multiple informants, including students' self-report questionnaires, clinical diagnostic
19
20 interviews of the students, parents' or guardians' self-report questionnaires, and structured
21
22 clinical interviews of the parents or guardians regarding any psychiatric comorbidity in their
23
24 children.
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30 31 Follow-up and retention strategy

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33 In an effort to maintain contact with iCURE study participants, we will send individual
34
35 reports annually via registered mail, and we will periodically send text messages about
36
37 general contents via cell phone to the participants. Once a year, we will send each
38
39 participant's survey results to their parents via registered mail, which will be called a "mental
40
41 health signal." This will include the mental health status regarding symptoms of Internet
42
43 game addiction, depression, anxiety, and ADHD, marked as red, yellow, and green traffic
44
45 signals, indicating symptom severity as assessed by both the self-report survey and the
46
47 clinical diagnosis. We will also provide referrals for treatment availability.
48
49

50
51 During this study, we are operating a 24-hour counseling helpline for the parents and
52
53 guardians. A clinical psychologist with more than 10 years of clinical experience specializing
54
55 in children and adolescents is conducting telephone consultations. This telephone counseling
56
57 is free and anonymous, providing parents with general counseling about their children, as
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4 well as specific counseling regarding gaming addiction.
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8 *Student self-report questionnaires*

9
10 Student data collection is conducted at the schools during school hours. The 7th-grade students
11 complete questionnaires using a web-based self-administration method. The 3rd- and 4th-grade
12 students complete the questionnaires in a class setting; a research assistant reads the questions
13 aloud, following a standard script, to aid comprehension and diminish time demands. In later
14 waves, all students will complete the questionnaires on their own, with a supervising research
15 assistant available to answer questions. During the baseline assessment, the questionnaires
16 took approximately 90–120 minutes to complete; later waves will take approximately 45–80
17 minutes. The student data collection at later waves will also be conducted at the schools
18 during school hours. For students who transfer to other schools, arrangements will be made to
19 complete the follow-up questionnaires, either by visiting their homes or via website access.
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35 *Interviewing parents*

36
37 At baseline, each parent or guardian completed a questionnaire and the Diagnostic Interview
38 Schedule for Children, Version 4 (DISC-IV). The DISC-IV is a highly structured diagnostic
39 interview used to assess psychiatric disorders in children and adolescents. We are including 7
40 of the 34 diagnostic assessments: generalized anxiety disorder, separation anxiety, obsessive-
41 compulsive disorder, major depression disorder, attention deficit disorder and attention deficit
42 hyperactive disorder (ADD/ADHD), oppositional defiant disorder, and conduct disorder.
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49

50 The DISC-IV was administered by trained interviewers at the participants' homes or at a
51 private space at the school, based on the participant's preference. The parent questionnaire
52 contained demographic questions and took 20 to 30 minutes to complete, and the DISC-IV
53 took 40 to 90 minutes. Parent or guardian survey is conducting only at baseline.
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Second-stage clinical diagnosis by mental health professionals

The clinical diagnostic interviews for IGD were conducted face-to-face by five psychiatrists and four Master's degree-level clinical psychologists with at least five years of training and clinical experience. The interviews assessed participants based on the nine DSM-5 IGD criteria, in accordance with the international consensus for IGD represented in the DSM-5¹⁹. Diagnoses were based on clinically significant functional impairments that substantially derived from gaming and not from any other psychiatric illnesses. Any psychiatric comorbidities were also thoroughly evaluated by the psychiatrists using the semi-structured tool of the Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version-Korean version (K-SADS-PL), which has been previously validated in Korean²⁴. Global functioning was assessed using the Children's Global Assessment Scale (GAS), based on the child's worst level of emotional and behavioral functioning in the past three months. The criterion for a second-stage clinical diagnosis is an Internet Game Use-Elicited Symptom Screen (IGUESS) total score of 6 or higher, either at baseline or at the follow-up waves. Additionally, random selection of 10% of the full cohort, stratified by the school, completed the clinical diagnostic interviews at baseline and the further follow-up waves. Anyone who responds insincerely with marking all of the same numbers to the IGUESS at every wave will be excluded to rule out false negatives. Anyone who reports a suicidal experience during the past year at any wave will be given diagnostic interviews. The clinical diagnostic interviews are being conducted one week after completion of the baseline study. The interviews are being conducted confidentially in private spaces at the participants' schools.

Sub-cohorts

Two sub-cohorts have been constructed. A representative sub-cohort consists of a randomly

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3
4 selected 10% of adolescents in the cohort. They will participate in the clinical diagnostic
5
6 interview every year to estimate the false negative rate and to evaluate the clinical course of
7
8 DSM-5–defined IGD based on clinical diagnosis. Additionally, a clinical evaluation sub-
9
10 cohort is comprised of those meeting three or more of the nine IGD criteria, as determined by
11
12 the clinical diagnostic interview at baseline and at each follow-up wave. The reason why they
13
14 were selected as a clinical evaluation sub-cohort was to observe the natural history or clinical
15
16 course of them even though they did not reach the DSM-5 IGD diagnostic criteria. Following
17
18 up this sub-cohort may reveal whether they actually turned out to be IGD or normal behavior.
19
20 The interviews will be conducted annually for 3 years to observe the clinical history,
21
22 remission, and recurrence rates.
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28 Measurement

29
30 The measurements using i-CURE are presented in Table 1.

31 32 *Demographic information*

33
34 Demographic characteristics were assessed at baseline. Sex, date of birth, family composition,
35
36 and number of siblings were obtained from the student assessment, and parental education
37
38 level, socio-economic status, parental marital status, parental education level, and parental
39
40 job were obtained from the parent or guardian assessments.
41
42

43 44 *Internet, gaming, and smartphone use*

45
46 Comprehensive assessments of participants' Internet, gaming, and smartphone usage were
47
48 performed, including questions regarding the first time of exposure, the average daily time
49
50 spent online, and gaming-related questions, such as online gaming type preference and
51
52 weekly playing time. We classified online games as role-playing games, shooter games,
53
54 simulation games, arcade games, and unknown.
55
56

57 58 *Regulated usage of smartphones or games*

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2
3
4 We assess school policies on possession and usage of smartphones and domestic regulations
5 of smartphone or game time.
6
7

8 *Internet Addiction Test (IAT)*

9
10 Young's IAT consists of 20 items rated on a 5-point Likert scale from *rarely* (1) to *always* (5),
11 with higher scores indicating more severe Internet addiction ²⁵.
12

13 *Korean Scale for Internet Addiction (K-Scale)*

14
15 To assess Internet addiction, we use the K-Scale-short form for adolescents, which were
16 developed in Korea. It is comprised of 20 items rated on a 4-point Likert scale, from 1 (*not at*
17 *all*) to 4 (*always*)²⁶.
18
19

20 *Internet Game Use-Elicited Symptom Screen (IGUESS)*

21
22 This instrument was created based on the nine DSM-5 IGD criteria. Students are instructed to
23 respond based on their gaming behavior within the last 12 months, with each item rated on a
24 4-point scale: 1=*strongly disagree*, 2=*somewhat disagree*, 3=*somewhat agree*, 4=*strongly*
25 *agree*).
26
27

28 *Self-reported version of structured clinical interview for Internet Gaming Disorder (SR-IGD)*

29
30 We use the SR-IGD to assess IGD with respect to occurrences over the past 6 months. The
31 assessment uses yes-or-no questions ²⁷.
32
33

34 *Short version of the Smartphone Addiction Scale (SAS-SV)*

35
36 We assessed smartphone addiction using the short version of the Smartphone Addiction Scale
37 (SAS-SV). The SAS-SV addresses the following 5 content areas with respect to the previous
38 year: (1) daily-life disturbance, (2) withdrawal, (3) cyberspace-oriented relationship, (4)
39 overuse, and (5) tolerance. It contains 10 items rated on a dimensional scale (1=*strongly*
40 *disagree* to 6=*strongly agree*). The total scores range from 10 to 60, with the higher scores
41 indicating greater degrees of smartphone addiction ²⁸.
42
43

44 *Children's Depression Inventory (CDI)*

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3
4 The Children's Depression Inventory (CDI) is a 27-item, self-rated, symptom-oriented scale
5 suitable for youths aged 7 to 17 years. It assesses cognitive, affective, somatic, and behavioral
6 symptoms, with items scored from 0 to 2, where 0 means *the symptom is not present*, 1 means
7 *the symptom is present and mild*, and 2 means *the symptom is present and marked*²⁹.
8
9

10 11 12 *Trait Anxiety Inventory for Children (TAIC)*

13
14 To examine trait anxiety, we used the Korean translation³⁰ of the Trait Anxiety Inventory for
15 Children (TAIC), which is part of the State-Trait Anxiety Inventory for Children (STAIC)
16 developed by Spielberger and colleagues (1973). The Korean TAIC is a 20-item inventory
17 that asks respondents to indicate how frequently, on a 3-point scale (1=*almost never* to
18 3=*almost always*), they feel worried, bothered, or nervous³¹..
19
20
21
22
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25

26 *Korean version of the ADHD Rating Scale (K-ARS)*

27
28 The Korean version of the ADHD Rating Scale (K-ARS) was used to assess ADHD which
29 was originally developed by DuPaul³². The K-ARS is a scale for ADHD symptom severity
30 composed of 18 items (9 items for inattention and 9 items for hyperactivity) scored from as 0
31 (*never or rarely*) to 3 (*very often*)³³.
32
33
34
35
36

37 *Diagnostic Interview Schedule for Children, Version IV (DISC-IV)*

38
39 In the current study, the DISC-IV was administered by a trained interviewer. The DISC-IV is
40 comprised of six domains of possible impairment present during a "time in the last year when
41 symptoms caused the most problems." These domains are (1) getting along with parent
42 caretakers, (2) participating in family activities, (3) participating in peer activities, (4)
43 academic/occupational functioning, (5) relationships with teachers, and (6) distress
44 attributable to symptoms. Each set of questions has a 2-part structure, the first determining
45 whether impairment is present, and the second measuring severity or frequency. We selected
46 an introductory module that includes demographic information (age, grade, names and ages
47 of siblings, and identification of caretakers and attachment figures). The remainder of the
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4 interview is organized into 3 modules, each containing related diagnoses (anxiety, mood, and
5
6 disruptive disorders)³⁴.
7

8 *Presence of suicidal ideation, suicide plans, and suicide attempts*

9
10 The presence of suicidal ideation, suicide plans, and suicide attempts is determined using the
11
12 following direct questions derived from the Structured Clinical Interview for DSM-IV Axis I
13
14 Disorders (SCID-I). Participants are asked whether they had seriously considered committing
15
16 suicide, made a plan to commit suicide, or attempted suicide during the past year. The
17
18 presence or absence of suicide ideation, plans, and attempts is based on the subject response
19
20
21 (yes or no)³⁵.
22
23

24 *Patient Health Questionnaire (PHQ-9)*

25
26 The PHQ-9 is a multipurpose instrument that assists in screening, diagnosing, and monitoring
27
28 depression severity. It incorporates the DSM-IV depression diagnostic criteria with other
29
30 leading major depressive symptoms into a brief nine-item, self-report tool. Respondents rate
31
32 the frequency of the symptoms over the last 2 weeks on a 4-point rating scale (*not at all* = 0;
33
34 *several days* = 1; *more than half of the days* = 2; *nearly every day* = 3)³⁶.
35
36

37 *Rosenberg's Self-Esteem Scale*

38
39 Rosenberg's Self-Esteem Scale has 10 items, each rated on a 5-point Likert scale, ranging
40
41 from 1 (*strongly disagree*) to 5 (*strongly agree*). The total score ranges from 10 to 50³⁷.
42
43

44 *Self-Control Scale*

45
46 Self-Control Scale is defined by Gottfredson and Hirschi (1990)³⁸. The 20-item scale is
47
48 divided into two self-control constructs: immediate and delayed satisfaction. Each item is
49
50 rated on a 4-point scale: (4) *strongly agree*, (3) *agree somewhat*, (2) *disagree somewhat*, and
51
52 (1) *strongly disagree*. Higher scores indicate lower self-control.
53
54

55 *Aggression Questionnaire (AQ)*

56
57 The Buss-Perry Aggression Questionnaire is a 29-item scale that measure four aspects of
58
59
60

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4 human aggression and hostile personality. Participants rate each item using a 5-point Likert
5 scale from 1 (*uncharacteristic of me*) to 5 (*very characteristic of me*)³⁹.

6
7
8 *Social Support Appraisals Scale: Child's Subjective Appraisal of Family, Peer, and Teacher*
9 *Support (SSAS)*

10
11 We use the Social Support Appraisals Scale: Child's Subjective Appraisal of Family, Peer,
12 and Teacher Support (SSAS) to address the adolescent participants' perceived support. It is a
13 41-item self-report instrument developed by Dubow et al. (1989)⁴⁰. Items are rated on a 5-
14 point Likert scale, from 1 (*never*) to 5 (*always*).

15
16
17 *Parent-Adolescent Communication Inventory (PACI)*

18
19 The Parent-Adolescent Communication Inventory (PACI) is a 40-item inventory used to
20 assess communication in the parent-adolescent relationship. There are two forms of the
21 inventory, one for parents and the other for adolescents. Scores range from 0 to 120, with
22 higher scores reflecting a greater degree of parent-adolescent communication⁴¹.

23
24 *The Children's Perception of Interparental Conflict Scale (CPIC)*

25
26 The CPIC uses a multiple-choice format with three possible responses: *true*, *sort of true*, and
27 *false*. Items are scored from 1 to 3, with 3 reflecting more negative forms of conflict and their
28 appraisal⁴².

29
30
31 *Revised Inventory of Parent and Peer Attachment (IPPA-R)*

32
33 The original IPPA was developed by Armsden and Greenberg (1987) to assess adolescents'
34 perceptions of the positive and negative affective and cognitive dimensions of relationships
35 with their parents and close friends. In particular, the inventory examines how well these
36 figures serve as sources of psychological security. Three broad dimensions are assessed:
37 degree of mutual trust, quality of communication, and alienation. Participants are asked to
38 rate each of the items on a 5-point Likert-scale from 1 (*never true*) to 5 (*always true*)⁴³.

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41 *Physical and mental health status*

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4 We assess physical pain experiences, such as in the hand, wrist, shoulder, or neck; dry eyes;
5
6 drinking and smoking habits during the past year; histories of physical illness, including
7
8 rheumatoid arthritis, lupus, diabetes mellitus; and psychiatric illness, including depression,
9
10 anxiety disorders, and ADHD. We also ask about sleep hours during the week and during
11
12 weekends.
13

14 15 16 17 Sample size estimation

18
19 We calculated the study sample size required to investigate whether overuse of Internet
20
21 gaming is a risk factor of IGD presence at the 2-year follow up. For a 15% prevalence of
22
23 exposure to 3 or more hours per day of Internet gaming, a 5% incidence of IGD at the 2-year
24
25 follow-up period, a relative risk of this risk factor for IGD of 2 (RR=2.0), and setting α at
26
27 0.05 and β at 0.20 (power of 0.80), a sample size of 2,559 is required. Considering a dropout
28
29 rate of 14%, the required sample size is estimated to be almost 3,000. We expect there will be
30
31 150 adolescents at high-risk for IGD (meeting 3 or more of the 9 DSM-5 IGD criteria) among
32
33 the 3,000 participants at baseline, and we estimate that 75 new IGD cases will be found at the
34
35 2-year follow-up⁴⁴.
36
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42 Strategies to minimize error and bias

43 44 *Online assessment system*

45
46 The participants log onto the study's website with unique authentication codes provided,
47
48 where they complete the online questionnaires. We use a branched algorithmic structure to
49
50 enhance the confidentiality and accuracy of responses and to reduce the risk of exposing
51
52 sensitive information.
53

54 55 *Training of the interviewers*

56
57 To administer the parent-guardian surveys, we recruited psychologists and nurses with
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4 Bachelor's or Master's degrees, and the research team provided them with training that
5
6 included information on Internet gaming addiction and communication skills, through a 2-day
7
8 (16-hour) training workshop. In addition to administering the surveys, the interviewers
9
10 reported on the status of the data collection and any problems and issues arising during the
11
12 interviews, at mandatory weekly meetings.
13

14
15 Prior to the diagnostic interviews and twice each year, all psychiatrists and clinical
16
17 psychologists attend a seminar about IGD diagnosis to increase inter-rater reliability and
18
19 diagnostic agreement. In the seminar, we review recent papers on IGD diagnosis and provide
20
21 mock cases in a video to enhance diagnostic concordance. Also, at the end of each day of
22
23 diagnostic interviews, all psychiatrists and clinical psychologists who participate in the
24
25 clinical diagnosis attend a case conference to discuss any ambiguous diagnoses and make
26
27 final determinations.
28
29

30 31 32 33 Statistical analyses plan

34
35 We will calculate the 2-year incidence, remission, and recurrence rates of IGD, with 95%
36
37 confidence intervals. We will investigate the cross-sectional and longitudinal associations
38
39 between exposures and outcomes using a logistic or linear regression model or a generalized
40
41 linear model, as appropriate. Models will include exposures to games, such as time spent
42
43 playing games, types of Internet games, and gaming-related activities, with IGD as the
44
45 outcome variable and covariates including socio-demographic, personal, social, and
46
47 environmental factors. Moderation tests will examine for differences in associations and
48
49 mediation tests will assess indirect effects based on socio-demographic, personal, social, and
50
51 environmental factors.
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56 57 58 **Ethics and dissemination**

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4 All procedures performed in studies involving human participants were in accordance with
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6 the ethical standards of the Institutional Review Board of The Catholic University of Korea
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8 (approval number: MC140NM10085) and with the 1964 Helsinki declaration and its later
9
10 amendments or comparable ethical standards. Written consent was received from all
11
12 participants and from one of the participants' parents or caregivers following an explanation
13
14 of the study, including confidentiality and freedom of choice to participate. All results will be
15
16 published in relevant peer-reviewed international scientific journals and presented at conferences, nationally and
17
18 internationally.
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21

22 23 **Discussion**

24
25 A major strength of this study is that it is conducted in a county with a particularly high
26
27 burden of IGD in adolescents. Korea has a high likelihood of exposure to games because
28
29 Korea plays a leading role in the development of the game industry and is one of the most
30
31 highly digitalized societies in the world. It provides a high-access environment for Internet
32
33 gaming, including PC rooms, which have broad-band Internet networks and are equipped
34
35 with the best performance computers in Korea. This makes Korea an optimal place to
36
37 perform a cohort study to characterize IGD.
38
39

40
41 We are screening 3rd-, 4th-, and 7th-grade students for IGD using both polychotomous and
42
43 dichotomous tools based on the nine DSM-5 IGD criteria. In addition, we are conducting
44
45 structured interviews using DISC-IV of the parents or guardians to assess participant
46
47 psychiatric comorbidities. Because the participants are early adolescents, we obtained their
48
49 mental health status through their parents or guardians. Self-reports can include false or
50
51 insincere reports, making evaluation of the IGD risk factors less accurate. To reduce this
52
53 effect, we have added a reverse scale to each self-report questionnaire.
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56
57 Another strength of this study is that the clinical diagnosis of IGD based on the DSM-5 is
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4 performed by qualified mental health specialists. Most prior studies have not been able to
5
6 also get a true clinical diagnosis along with the screening tool scores, so this study will
7
8 provide needed validity data. Participants included those considered positive for IGD, defined
9
10 as scores of 6 or higher on IGUESS, as well as a reference group of a random selection of 10%
11
12 of the participants. We have constructed two sub-cohorts from those who have participated in
13
14 the clinical diagnosis: a representative and a high-risk cohort. The representative sub-cohort
15
16 consists of 10% randomly selected adolescents from the full cohort. They participate in the
17
18 clinical diagnostic interview every year in order to estimate the false negative rate and to
19
20 evaluate the clinical course of IGD, observed via the diagnostic interviews. The high-risk
21
22 sub-cohort is comprised of participants meeting 3 or more of the 9 IGD criteria, based on the
23
24 clinical diagnostic interviews at baseline and each follow-up wave. The high-risk sub-cohort
25
26 is similar to a dynamic cohort. The suggested diagnostic criteria of IGD in DSM-5 is to meet
27
28 5 or more of the 9 IGD criteria; however, we plan to follow those adolescent participants
29
30 meeting 3 or more clinical diagnostic interview in any year in order to investigate the course
31
32 of IGD at syndromal and subsyndromal levels.
33
34
35

36
37 This study aims to clarify the natural and clinical courses of IGD based on the DSM-5
38
39 suggested diagnostic criteria in order to empirical validate the criteria and to evaluate the risk
40
41 and predictive factors in adolescents based on the IGD diagnostic criteria. This study will
42
43 contribute to establishing standardized IGD diagnostic criteria and to providing scientific
44
45 evidence regarding the proposed DSM-5 IGD diagnostic criteria.
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53 **Keywords:**

54 Internet gaming disorder, adolescents, cohort, protocol
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56 **Lists of Abbreviations**

57 Aggression Questionnaire (AQ)
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4 Attention Deficit Hyperactivity Disorder (ADHD)
5 Children's Depression Inventory (CDI)
6 Children's Perception of Inter-parental Conflict Scale (CPIC)
7 Diagnostic and Statistical Manual of Mental Disorders 5th version (DSM-5)
8 Diagnostic Interview Schedule for Children, Version IV (DISC-IV)
9 Global assessment scale (GAS)
10 International Classification of Diseases 10th version (ICD-10)
11 International Classification of Diseases 11th version (ICD-11)
12 Internet Game Use-Elicited Symptom Screen (IGUESS)
13 Internet gaming disorder (IGD)
14 Internet user Cohort for Unbiased Recognition of gaming disorder in Early adolescents
15 (iCURE)
16 Kiddie-Schedule for Affective Disorders and Schizophrenia-Present and Lifetime Version-
17 Korean version (K-SADS-PL)
18 Korean version of the ADHD Rating Scale (K-ARS)
19 Parent-Adolescent Communication Inventory (PACI)
20 Parent-Adolescent Communication Inventory (PACI)
21 Parenting attitude test (PAT)
22 Patient Health Questionnaire (PHQ-9)
23 Post-traumatic stress disorder (PTSD)
24 Revised Inventory of Parent and Peer Attachment (IPPA-R)
25 Smartphone Addiction Scale (SAS-SV)
26 Social Support Appraisal Scale (SSAS)
27 Standard Patients Evaluation of Eye Dryness Questionnaire (SPEED)
28 Structured Clinical Interview for DSM-IV Axis I Disorders (SCID-I)
29 Self-reported version of structured clinical interview for Internet Gaming Disorder (SR-IGD)
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39

40 **Availability of data and materials**

41 Not applicable. This protocol was not included any participants data.
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43

44 **Authors' contribution:**

45 HJ conducted the analyses and led the writing of the manuscript. HWY guided and
46 supervised the writing of the manuscript. HWY, HJ, and SJ developed and proposed the basic
47 idea of the study. HWY, HJ, SJ, EK, HS and HH contributed to conducting the study. SL, HL,
48 YK, SB, and JC conducted diagnostic interviews. BK guided to performance DISC
49 assessment. DAG advised to construct study design. DAG and MNP reviewed scientific and
50 proof reading of the manuscript. All authors contributed editorial comments on the
51 manuscript.
52

53 **Conflict of interest:**

54 The authors declare no conflicts of interest with respect to the content of the manuscript..
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57 **Consent for publication**

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4 Not applicable.
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Table 1. Measurement tools in each wave

Categories	Measures	Source	Wave			
			T1	T2	T3	T4
Exposure variables	Exposure time to internet, smart phone, and online game	student/parent	√	√	√	√
	Internet, smart phone, and online game using behaviors	Student	√	√	√	√
Diagnosis	IAT	Student	√			
	K-scale	Student	√			
	IGUESS	Student	√	√	√	√
	SR-IGD	Student	√		√	√
	SAS-SV	Student	√	√	√	√
Psychiatric comorbidities	CDI	Student	√	√	√	√
	TAIC	Student	√	√	√	√
	K-ARS	Parent	√			
	DISC-IV	Parent	√			
	Suicidality	Student	√	√	√	√
	PHQ-9	Parent	√			
Personal factors	Rosenberg's Self-Esteem Scale	Student	√			
	Self-control scale	Student	√			
	AQ	Student	√	√	√	√
	Demographic information	Student/parent	√			
	Academic achievement	Student/parent	√	√	√	√
Environmental factors	School policy on having smart phone use in school	Student	√	√	√	√
	PACI	Student	√			
	Marriage satisfaction	Parent	√			
	IPPA-R	Student	√			
	Perceived Parenting Competence	Parent	√			
Social factors	Online gaming rule in home	Parent	√	√	√	√
	Social network	Student	√			
	Bullying scale	Student	√			
	SSAS	Student	√			
Health consequences	Physical health	Student/parent	√			
	Mental health	Student	√			

Internet Addiction Test (IAT); Korean Scale for Internet Addiction (K-Scale); Internet Game Use-Elicited Symptom Screen (IGUESS); Self-reported version of structured clinical interview for Internet Gaming Disorder (SR-IGD); Short version of the Smartphone Addiction Scale (SAS-SV); Children's Depression Inventory (CDI); Trait Anxiety Inventory for Children (TAIC); Korean version of the ADHD Rating Scale (K-ARS); Diagnostic Interview Schedule for Children, Version IV (DISC-IV); Patient Health Questionnaire (PHQ-9); Aggression Questionnaire (AQ); Parent-Adolescent Communication Inventory (PACI); Revised Inventory of Parent and Peer Attachment (IPPA-R); Social Support Appraisals Scale: Child's Subjective Appraisal of Family, Peer, and Teacher Support (SSAS)