ISRCTN95010035 https://doi.org/10.1186/ISRCTN95010035

Cognitive training as treatment for games or other types of internet addiction

Submission date
08/12/2021

Recruitment status
No longer recruiting

Registration date
14/12/2021

Overall study status
Completed

Last Edited
11/05/2023

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
The prevalence of behavioral addiction, such as gaming disorder and other types of internet addiction (pornography, online gambling) keeps on increasing in the last few years, especially during the COVID-19 pandemic. Up to date, research using brain imaging in people with gaming disorders has suggested functional abnormalities in the brain reward system. These changes are reflected in disturbance of cognitive functions such as concentration, self urges control, planning ability, and language comprehension. Several studies reported that people with gaming disorder and other types of internet addiction would have a lower overall quality of life (physical, psychological, and social). The current study assumed that by improving cognitive functions, the quality of life could also be improved. Cognitive Training (CT) is a nonpharmacological approach involving a series of regular mental activities designed to help maintain or even increase a person's cognitive (thinking) abilities. CT interventions have been developed and proven to be effective in individuals with substance dependence. Psychotherapy combined with CT has been reported to be more effective in improving working memory and modifying thinking errors, thereby improving self-regulation and impulse control, compared to no treatment at all. The improvement could also be confirmed by examining the functional activity of the brain area before and after CT interventions. Therefore, this study aims to determine the effectiveness of CT intervention in combination with psychotherapy using fMRI measurement.

Who can participate?
All patients who attended the addiction clinic in dr. Cipto Mangunkusumo General Hospital (RSCM), aged 13 to 24 years old, and who do not have mental retardation or acute phase of a psychotic disorder.

What does the study involve?
Participants will be allocated to one of two groups, with an equal chance of being in either group (like tossing a coin). Both investigators and participants will not know whether they are in the intervention group or control group. The participants allocated to the intervention group will be provided with the Cognitive Training (CT) application modalities along with Treatment As Usual (TAU) which is Cognitive Behavioral Therapy (CBT). The Cognitive Training will be given in 12 sessions with each lasting for 30-40 min. The CT sessions will be applied once a week for a total

duration of 12 weeks. CBT is an individual outpatient session every week for 3 months (12 sessions in total), facilitated by a psychiatrist, and lasts about 45-60 min. Participants in the control group will receive treatment as usual (TAU) in the form of Cognitive Behavioral Therapy (CBT) only. Participants will also be compared against a healthy control group who are not affected by addiction and will receive no treatment.

What are the possible benefits and risks of participating?
The benefits of participation are that the subjects could get a comprehensive psychiatric examination, including examination of the brain functions using fMRI, as well as obtaining therapy (in the form of CT and/or psychotherapy) given by addiction psychiatrists. The therapy could possibly improve the quality of life and interpersonal relationships as well as participants' work/academic achievements. The risk of participation involves the side effects of fMRI examination. fMRI procedure does not cause serious side effects as it does not use radiation and contrasts. Side effects that may arise are discomfort related to the examination tool because it is narrow, makes a reasonably loud sound, and the procedure takes a long time. The participant will be allowed to be accompanied by the research team or a family member if they feel anxious.

Where is the study run from?
The Addiction Clinic dr. Cipto Mangunkusumo General Hospital, Jakarta (Indonesia)

When is the study starting and how long is it expected to run for?
From April 2020 to January 2023

Who is funding the study?
The Faculty of Medicine Universitas Indonesia (Indonesia) and the Indonesian Ministry of Research and Technology, National Research and Innovation Agency (Indonesia)

Who is the main contact?
Dr Kristiana Siste
kristiana.siste@ui.ac.id

Contact information

Type(s)
Scientific

Contact name
Dr Kristiana Siste

ORCID ID
http://orcid.org/0000-0001-7435-6243

Contact details
Jalan Salemba Raya Nomor 6
Jakarta
Indonesia
10430
+62 (0)87782516771
kristiana.siste@ui.ac.id

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
KET-885/UN2.F1/ETIK/PPM.00.02/2020

Study information

Scientific Title
The identification of risk factors and vulnerability of brain functional changes as predictor model development and therapy for gaming disorder or other types of internet addictions: developing high-quality Indonesian adolescents

Acronym
BFC

Study objectives
1. Cognitive training (CT) sessions and cognitive behavioral therapy (CBT) reduce the severity of internet addiction or gaming disorder than CBT alone.
2. CT and CBT are more effective than CBT alone in changing the brain functional connectivity after the intervention.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/08/2020, The Ethics Committee of the Faculty of Medicine, University of Indonesia - Cipto Mangunkusumo Hospital (Jalan Salemba Raya No.6, Jakarta 10430, Indonesia; +62 (0) 213912477; humas@fk.ui.ac.id), ref: 20-08-0899

Study design
Single-center randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)

Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Gaming disorder or internet addiction

Interventions
Participants will be selected randomly from the sample population and according to the inclusion and exclusion criteria and divided into three arms: the experimental arm, the control arm, and the healthy control arm. 6 participants for arm 1 (experimental: CBT and CT), 6 participants for arm 2 (control: CBT only), and 5 participants for arm 3 (healthy control, no intervention).

The participants allocated to the intervention arm will be provided with the Cognitive Training (CT) application modalities along with Treatment As Usual (TAU) which is Cognitive Behavioral Therapy (CBT). The Cognitive Training will be done in 12 sessions with each lasting for 30-40 minutes. The CT sessions will be applied once a week for a total duration of 12 weeks. CBT is an individual outpatient session every week for 3 months (12 sessions in total), facilitated by a psychiatrist, and lasts about 45-60 minutes. Participants in the control arm will receive treatment as usual (TAU), consisting of Cognitive Behavioral Therapy (CBT) from the psychiatrists.

The participants are required to fill several questionnaires, including demographic questionnaire, Kuesioner Diagnostik Adiksi Internet (KDAI), The Gaming Engagement Screener (GAMES), Strength and Difficulties Questionnaire (SDQ), Rosenberg Self Esteem Scale (RSES), Temperament and Character Inventory (TCI), BRIEF COPE, Cognistat, Attention and Visuo-Spatial Assessment (TMT-B), Balloon Analogue Risk Test (BART), MoCA-Ina, Internet Sex Screening Test (ISST), and South Oaks Gambling Screen (SOGS).

Participants in arm 1 and arm 2 would undergo fMRI before and after treatment. fMRI examination with a 3.0 Tesla MRI machine and multiple sequences (eg: T1, T2, DWI) was performed before (baseline) and after (follow-up) the intervention followed by post-imaging analysis to assess the density and volume of the substantia nigra and white matter. Healthy control subjects (arm 3) will undergo all examinations but will not follow the intervention and will not be performed fMRI after 3 months. The examination will involve brain areas in the form of regions of interest, namely bilateral intraparietal sulcus, medial prefrontal cortex, frontal eye field, middle frontal gyrus, nucleus accumbens, left inferior parietal lobe. Data that will be obtained undergo pre-processing (using FMRIB's ICA-based X-noisefier©) and functional connectivity analysis (using CONN-fMRI functional connectivity toolbox©). Post-imaging analysis of fMRI results to see the difference between the dependency group and the control group and to see the difference in changes in the two clinical trial arms.

Intervention Type
Behavioural

Primary outcome measure
1. The severity of gaming disorder and internet addiction measured by KDAI and GAMES results of the experimental and control group before and after the intervention

2. Brain functional connectivities changes measured using fMRI before the intervention (arm 1, arm 2, and arm 3) and after intervention (arm 1 and arm 2)

Secondary outcome measures
1. Cognitive function measured using Cognistat Cognitive Assessment at pre and post-intervention
2. Cognitive function is measured using MoCA-Ina at pre and post-intervention
3. Presence of online pornography addiction measured using ISST at pre-intervention
4. Presence of online gambling addiction measured using SOGS at pre-intervention
5. Psychiatry diagnosis measured using Mini ICD-10 at pre-intervention
6. Self-esteem measured using RSES at pre and post-intervention
7. Coping strategies measured using Brief COPE at pre and post-intervention
8. Attention and visuospatial function measured using Trail Making Test B (TMT-B) at pre and post-intervention
9. Risk-taking behavior measured using the Balloon Analogue Risk Task (BART) at pre and post-intervention
10. Personality traits measured using TCI at pre-intervention
11. Behavioural and emotional difficulties measured using the Strength and Difficulties Questionnaire (SDQ) at pre and post-intervention

Overall study start date
29/04/2020

Completion date
15/01/2023

Eligibility

Key inclusion criteria
1. Attended the addiction clinic in dr. Cipto Mangunkusumo General Hospital (RSCM)
2. Aged between 13 and 24 years (WHO youth criteria)

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
6 participants for arm 1 (experimental: CBT and CT), 6 participants for arm 2 (control: CBT only), and 5 participants for arm 3 (healthy control, no intervention)

Total final enrolment
19

Key exclusion criteria

Any of the following, identified through a psychiatric interview (MINI ICD-10):
1. Mental retardation
2. The acute phase of psychotic disorder

Date of first enrolment
12/12/2021

Date of final enrolment
15/10/2022

Locations

Countries of recruitment
Indonesia

Study participating centre
University of Indonesia - Cipto Mangunkusumo Hospital
Psychiatry Department
Faculty of Medicine
Jalan Salemba Raya Nomor 6
Jakarta
Indonesia
10430

Sponsor information

Organisation
Ministry of Research, Technology and Higher Education

Sponsor details
National Research and Innovation Agency
BPPT Building II
2nd Floor
Jl. MH. Thamrin 8
Jakarta
Indonesia
10340
+62 (0)213169688
drpm@ui.ac.id

Sponsor type
Government

Website

http://international.ristekdikti.go.id/

Funder(s)

Funder type
Other

Funder Name
Dede Djuhana, Ph.D

Results and Publications

Publication and dissemination plan
Current publication and dissemination plan as of 10/05/2023:
Planned to publish the study in Q1 journal

Previous publication and dissemination plan:
Planned to publish the study in PLoS ONE

Intention to publish date
01/10/2024

Individual participant data (IPD) sharing plan
Data are available on request from the Ethics Committee of the Faculty of Medicine University of Indonesia for researchers who meet the criteria for access to confidential data. Data requests should be submitted to ec_fkui@yahoo.com.
The informed consent form states that data will only be available to others in an encrypted and password-protected institutional online data repository.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request