Establishing A Digital-Assisted Parenting Intervention (DaPI) in Promoting Children Mental Health

Protocol summary

Study aim
To examine the effectiveness of DaPI on parenting (i.e., parenting styles, parental self-efficacy and self-esteem, and parent mental health) and family relations (i.e., parent-adolescent and interparental conflicts, and family cohesion) in promoting children mental health via an 8-week randomised two-arm controlled trial.

Design
Two arm, community based, parallel group, single blind, randomised controlled trial

Settings and conduct
When parents submit their pre-intervention (baseline) assessment, they will be randomly assigned into the intervention or control group. Parents will find out their assignment: the intervention group will have immediate access, while those in the control group will have a 12 weeks’ delay to the program. Parents in the intervention and control groups will complete assessments at post-intervention (8 weeks later) and 1 month follow-up. Allocation is concealed from participants and care givers prior to assignment. The outcome assessor and data analyser will be blinded throughout the trial as they are not involved in the assignment of groups or the online program.

Participants/Inclusion and exclusion criteria
Inclusion: a) Parents who owned a smart phone, tablet or computer and have access to the Internet. c) Parents who are willing to participate and provide information at scheduled follow-up points. d) Parents who have good command and understanding of the Malay language. Exclusion: a) Parents who are digital illiterate. b) Parents who have children with developmental delays. c) Parents who are currently receiving professional assistance for their own and/or their child’s mental health problems.

Intervention groups
Group (intervention) receives the online Digital-assisted Parenting Intervention (DaPI) Group (control) Waitlisted and receives the DaPI after completion of the trial

Main outcome variables
Parenting, family relations and adolescents’ mental health

General information

Reason for update
Acronym
DaPI (Digital-assisted Parenting Intervention)

IRCT registration information
IRCT registration number: IRCT20211129053207N1
Registration date: 2022-01-29, 1400/11/09
Registration timing: prospective

Last update: 2022-01-29, 1400/11/09
Update count: 0

Registration date
2022-01-29, 1400/11/09

Registrant information
Name
Anis Raihan Dzeidee Schaff

Name of organization / entity
Universiti Putra Malaysia

Country
Malaysia

Phone
+60 3-9769 2541

Email address
gs61229@student.upm.edu.my

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-01, 1400/11/12

Expected recruitment end date
2022-05-01, 1401/02/11

Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Establishing A Digital-Assisted Parenting Intervention (DaPI) in Promoting Children Mental Health

Public title
Establishing A Digital-Assisted Parenting Intervention (DaPI) in Promoting Children Mental Health

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Parents who owned a smart phone, tablet or computer and have access to the Internet. Parents who are willing to participate and provide information at scheduled follow-up points. Parents who have good command and understanding of the Malay language.

Exclusion criteria:
Parents who are digital illiterate. Parents who have children with developmental delays. Parents who are currently receiving professional assistance for their own and/or their child’s mental health problems.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
- Outcome assessor
- Data analyser

Sample size
Target sample size: 300

Randomization (investigator’s opinion)
Randomized

Randomization description
A project manager will be responsible to execute the randomization as to ensure blinding. Using simple random technique, each participant will be assigned with unique identification number generated by a random number generator using a 1:1 proportion. The participants will then be assigned to either the Digital-assisted Parenting Intervention (DaPI) or to the control group (i.e., waitlisted and will receive the intervention 12 weeks later).

Blinding (investigator’s opinion)
Single blinded

Blinding description
The outcome assessor and data analyser will be blinded because they are not involve with the allocation of groups or the online intervention. Data will be collected at pre-intervention (prior to group assignment), post-intervention (8-weeks) and 1 month follow up.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee for Research Involving Human Subjects Universiti Putra Malaysia (JKEUPM)

Street address
Jalan Universiti 1 Serdang, Seri Kembangan

City
Serdang

Postal code
43400

Approval date
2021-07-02, 1400/04/11

Ethics committee reference number
JKEUPM-2021-161

Health conditions studied

1

Description of health condition studied
Mental health

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Parenting styles

Timepoint
Before intervention, post-intervention (8 weeks), and 1 month follow-up

Method of measurement
Measured using the Parenting Scale by Arnold, O'Leary, Wolff, and Acker (1993)

2

Description
Parental self-efficacy

Timepoint
Before intervention, post-intervention (8 weeks), and 1 month follow-up

Method of measurement
Measured using the Child Adjustment and Parent Efficacy Scale by Morawska, Sanders, Haslam, Filus, & Fletcher (2014)

3

Description
Parent mental health

**Timepoint**
Before intervention, post-intervention (8 weeks), and 1 month follow-up

**Method of measurement**
Measured using the Depression Anxiety Stress Scales-21 (Lovibond & Lovibond, 1995)

---

**Secondary outcomes**
empty

**Intervention groups**

**1 Description**
Intervention Group: Parents in the intervention group will be given immediate access to the DaPI program. Parents will be emailed log in details and instructions to the program. They will be prompted to complete the program within 8 weeks (at which time post-intervention assessment will be conducted regardless of the number of sessions completed). DaPI will be covered in 8 sessions. The content of the sessions includes fostering positive relationship with child; fostering child’s optimal growth; fostering effective family functioning; fostering parent-child relationships; fostering parents’ mental health; and fostering child’s mental health. Parents will be guided with effective parenting skills through various techniques (i.e., written materials, videos, interactive activities, and feedback report on parenting behaviors). Each session will be delivered once a week and take roughly around 30 to 40 minutes depending on the time parents spend on the tasks in each session. Parents can access the program at their own convenience. Parents will also be able to access links to evidence-based parenting support and informational resources provided in each session. Throughout the 8-week intervention period, parents will be contacted via email if no logged-on activity is detected to the program.

**Category**
Behavior

**2 Description**
Control group: Parents in the control (waitlist) group will receive no treatment during the trial but will be given access (12 weeks later) to the DaPI program once the trial ended.

**Category**
N/A

**Recruitment centers**

**1 Recruitment center**

- **Name of recruitment center**
  Online via Social Media (i.e., Instagram and Facebook)

- **Full name of responsible person**
  Dr. Nor Sheereen Zulkefly

- **Street address**
  Department of Psychiatry, Faculty of Medicine and Health Sciences, Universiti Putra Malaysia

- **City**
  Serdang

- **Postal code**
  43400
Phone  
+60 3-9769 2541 
Email  
sheereen@upm.edu.my 

Sponsors / Funding sources 

1 
Sponsor 
Name of organization / entity 
Universiti Putra Malaysia 
Full name of responsible person 
Dr Nor Sheereen Zulkefly 
Street address 
Jalan Universiti 1 Serdang, Seri Kembangan 
City  
Serdang 
Postal code 
43400 
Phone  
+60 3-9769 2541 
Email  
sheereen@upm.edu.my 
Web page address  
https://www.upm.edu.my/ 
Grant name 
Fundamental Research Grant Scheme (FRGS) 
Grant code / Reference number 
05-01-202275FR 
Is the source of funding the same sponsor organization/entity? 
No 
Title of funding source 
High Education Ministry 
Proportion provided by this source 
100 
Public or private sector 
Public 
Domestic or foreign origin 
Domestic 
Category of foreign source of funding 
empty 
Country of origin 
Type of organization providing the funding 
Other 

Person responsible for general inquiries 

Contact 
Name of organization / entity 
Universiti Putra Malaysia 
Full name of responsible person 
Dr Nor Sheereen Zulkefly 
Position 
Senior Lecturer 
Latest degree 
Ph.D. 
Other areas of specialty/work 
Psychology 
Street address 
Jalan Universiti 1 Serdang, Seri Kembangan 
City  
Serdang 
Province 
Selangor 
Postal code 
43400 
Phone  
+60 3-9769 2541 
Email  
sheereen@upm.edu.my 
Web page address  
https://www.upm.edu.my/ 

Person responsible for scientific inquiries 

Contact 
Name of organization / entity 
Universiti Putra Malaysia 
Full name of responsible person 
Dr Nor Sheereen Zulkefly 
Position 
Senior Lecturer 
Latest degree 
Ph.D. 
Other areas of specialty/work 
Psychology 
Street address 
Jalan Universiti 1 Serdang, Seri Kembangan 
City  
Serdang 
Province 
Selangor 
Postal code 
43400 
Phone  
+60 3-9769 2541 
Email  
sheereen@upm.edu.my 
Web page address  
https://www.upm.edu.my/ 

Person responsible for updating data 

Contact 
Name of organization / entity 
Universiti Putra Malaysia 
Full name of responsible person 
Dr Nor Sheereen Zulkefly 
Position 
Senior Lecturer 
Latest degree 
Ph.D. 
Other areas of specialty/work 
Psychology 
Street address 
Jalan Universiti 1 Serdang, Seri Kembangan 
City  
Serdang 
Province 
Selangor 
Postal code
<table>
<thead>
<tr>
<th>Sharing plan</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Deidentified Individual Participant Data Set (IPD)</strong></td>
</tr>
<tr>
<td>Undecided - It is not yet known if there will be a plan to make this available</td>
</tr>
<tr>
<td><strong>Study Protocol</strong></td>
</tr>
<tr>
<td>Yes - There is a plan to make this available</td>
</tr>
<tr>
<td><strong>Statistical Analysis Plan</strong></td>
</tr>
<tr>
<td>Yes - There is a plan to make this available</td>
</tr>
<tr>
<td><strong>Informed Consent Form</strong></td>
</tr>
<tr>
<td>Yes - There is a plan to make this available</td>
</tr>
<tr>
<td><strong>Clinical Study Report</strong></td>
</tr>
<tr>
<td>Yes - There is a plan to make this available</td>
</tr>
<tr>
<td><strong>Analytic Code</strong></td>
</tr>
<tr>
<td>No - There is not a plan to make this available</td>
</tr>
</tbody>
</table>

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
All collected deidentified IPD during the trial

**When the data will become available and for how long**
Beginning 3 months and ending 5 years after publication

**To whom data/document is available**
Only available for personnel working in academic institutions or related mental health services

**Under which criteria data/document could be used**
Any purpose. Proposal / request should be directed to Dr Nor Sheereen Zulkefly at sheereen@upm.edu.my. To gain access, requestor will need to sign a data access agreement

**From where data/document is obtainable**
Proposal / request should be directed to Dr Nor Sheereen Zulkefly at sheereen@upm.edu.my.

**What processes are involved for a request to access data/document**
Request should be made via email, directed to Dr Nor Sheereen Zulkefly, stating purpose of request and plans on how to use the data.

**Comments**