Royal Holloway University of London

DClinPsy

Full Proposal (September 2024 version)

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Project title: A highly personalised process-based psychological intervention for paediatric headache cases: An idiographic ecological momentary study with weekly feedback provision

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Summary of project

This project will use a brief and highly personalised psychological intervention for adolescents experiencing headaches. We aim to understand how weekly progress based on participants' real data can help adolescents learn skills to cope with headaches. We will first proceed to an initial assessment of adolescents' (n=12) headache experiences. We will then formulate a diagram to identify central problem areas, or *processes,* relevant to adolescents' headaches. Based on this, we will then deliver a

brief, highly personalised intervention focused on learning adaptive psychological skills and coping responses to headaches. The intervention will consist of 5 weekly 30-minute 1-to-1 online sessions to address headache-related specific areas of concern, using already known psychological interventions under the Cognitive Behavioural Therapy (CBT) umbrella term (including Acceptance and Commitment Therapy)

During data collection, adolescents at set intervals will be prompted to complete brief online questionnaires on their smartphones using an app called mPath and Qualtrics. The questionnaires will be personalised and will measure specific psychological processes identified as target areas for each individual. This longitudinal data will then be used to analyse change in key processes within each individual. We will also measure whether there is an overall reduction in headache related disability and improvement of daily life following the intervention's completion.

Background & Aims of the project

Paediatric primary headache is a highly prevalent medical condition, experienced by more than 62% of children and adolescents worldwide (Onofri et al., 2023). The burden of headaches includes impairment in daily functioning at school and social/leisure activities (Kashikar-Zuck et al. 2013), and an impact on adolescents' quality of life (Larsson et al., 2018).

Albeit the notable impact of headaches, at present, psychological interventions show only small to medium effect sizes on improving headaches' impairment and quality of life (Dudeney et al., 2022). Further, treatment progress has been stagnating. Almost half of those receiving CBT for paediatric headache management, the recommended psychological intervention for headache (Fisher et al. 2018), show reductions in disability and improvements in functioning (Eccleston et al. 2014), indicating that

existing forms of treatment delivery do not always meet individual needs (Kroon Van Diest & Powers, 2019).

Personalised interventions can optimise the existing psychological interventions for paediatric populations by addressing the needs of adolescents during their daily life. A recent systematic review provides evidence in favour of personalising interventions for improved clinical outcomes (Nye et al. 2023), yet research allowing personalization in treatment in paediatric populations is lacking.

Process-Based Therapy (PBT; Hayes et al, 2019) leverages an ongoing functional analysis during treatment by collecting repeated sampling data from an individual's context of living, and based on this, returns weekly personalised feedback. This ongoing dynamic assessment and formulation process can guide therapists to regularly track changes and personalise interventions based on this information. PBT seems promising for optimising paediatric headache therapies where adolescents are heterogenous and have differing needs (Knestrick et al., 2022). Rather than being a new therapy model, PBT is predominantly a different approach to delivering therapy, which focuses on personalised CBT-based interventions to target key processes of change, rather than packaged, disorder-specific and protocol-driven interventions (McCracken et al., 2022).

A distinct aspect of PBT intervention is ongoing data collection, using methods such as Ecological Momentary Assessment (EMA). Using EMA, we will repeatedly sample symptoms, coping with headache responses, and relevant pain-related behaviours. EMA collects data that captures frequent momentary information from adolescents in the context of their lives, longitudinally (Hedeker et al., 2012). It also helps adolescents increase self-awareness, insight, and self-management of their

headache difficulties (Folkersma et al. 2021). In this study, we will use EMA to collect weekly data, which will inform progress tracking and allow personalised treatment trajectory.

Aim of the project and research question

The objective of this project is to construct idiographic case conceptualisations and deliver brief personalised interventions, guided by weekly data that will inform the course of the intervention. This study will focus on both the pilot efficacy and process of change examination of a highly personalised intervention, collecting baseline, weekly, post-intervention and follow-up data.

Our research questions are:

(a) Is a highly personalised intervention with weekly feedback provision effective in lowering headache disability and improving headache interference?

(b) Does a personalised intervention lead to changes in clinically targeted psychological processes, personalised goals and headache activity (outcomes)?

Plan of investigation

Design

This is a single-case experimental design (SCED) study, with concurrent multiple baselines within-subjects. We will use an AB design, where baseline (A) will always precede the intervention (B) phase for each participant. This design allows participants to act as their own control (Krasny-Pacini & Evans, 2018), whilst also maintaining experimental control. We will follow the SCRIBE statement (Tate et al., 2016) to guide the reporting of this SCED design.

Each participant will partake in a baseline data collection, between 1 to 2 weeks before we deliver the intervention. Participants will not be able to begin any psychological intervention for headaches during the study. Below, we present all the phases of the study.

As per guidance from previous REC feedback, the below protocol has been briefly piloted and reviewed with two adolescent experts by experience (EBEs). In a series of meeting, we tested several components of the following design and we proceeded with minor amendments based on their feedback. Their feedback was used to inform the below study protocol.

Phase 0-A: Screening.

The participating NHS clinics will identify and screen potential participants using the inclusion criteria. The partnering NHS clinics will provide some information about the aims and objectives of the study to adolescents and their parents/ carers. The participants will be given a flyer containing the QR code link to Qualtrics, to begin the onboarding process.

Phase 0-B: Enrolment.

Using a QR link to a Qualtrics survey, participants (and their caregiver, if they are aged 12-16) will view the study information sheet and proceed to the consent/assent form, should they wish to participate. Consent will be obtained electronically via Qualtrics. Participants will receive a copy of the information sheet and completed consent/assent form via email. Upon gaining consent, we will contact participants to begin Phase 1.

Phase 1: pre-baseline.

Participants will spend a total of 1-2 weeks completing an online questionnaire (Process Based Assessment Tool; PBAT). Participants will receive completion prompts via the mPath app, on 3-4 days per week, and the questionnaire will take up to 3-4 minutes to complete. The PBAT questionnaire will collect data to track how adolescents cope with their headaches. This information will help the research team to develop the personalised plan for the psychological intervention in Phase 4 (described further on).

Phase 2: Personalisation and case conceptualization.

We will meet with each adolescent online for 1 hour to collect further information using an intake assessment form (see the attached "Intake assessment form"). The form will assess headache history and coping responses. The research team will combine the information gathered in phase 1 and phase 2 to create a case conceptualisation. We will also create some brief goals for treatment and will identify key target processes (e.g., psychological coping responses, such as learning what to do during a headache episode) for the personalised intervention. We will collaboratively select 2-3 most personally relevant items from the previously completed PBAT questionnaire (in phase 1), which will form part of further data collection. These questionnaire items will be those deemed to be most relevant to the adolescents' presenting headache concerns, and these will guide the focus of the upcoming intervention. Finally, in Phase 2 we will introduce the upcoming data collection schedule which is described in Phase 3 below.

Phase 3: baseline data.

Participants will begin the Ecological Momentary Assessment (EMA), which they will complete 2-3 times per day, on 3- 4 days per week. The participants will be sent completion prompts via the mPath app. The questionnaires will take up to 2 minutes to complete each time. As per feedback from experts by experience, data collection will be distributed over several days per week to reduce participant burden (e.g., Monday, Wednesday and Friday). At this stage, participants will be completing both primary outcome measures (headache activity, progress towards the personalised goal, and coping with headache), and their personalised PBAT items. Once per week, participants will also receive a questionnaire assessing headache interference and headache-related disability.

Phase 4: intervention and further data gathering.

Each participant will be invited to attend up to 5 weekly online brief therapy sessions, lasting 30 minutes each, to work on the specific target processes identified in Phase 2. The personalised interventions will be drawn from already known evidence-based CBT-based treatments for headache

management. Clinical supervision during this treatment phase will be provided by the lead project supervisor who holds extensive clinical and research experience in chronic headaches. Due to the intervention being highly personalised, adherence to a specific treatment protocol will not be measured. Additionally, we will administer a Client Feedback Form at the final session.

Participants will begin interventions at different time points, in line with the Multiple-Baseline SCED Design. This will mean that some participants will spend longer completing Baseline data before they begin the intervention phase. We expect the baseline period to be no longer than 2 weeks at most, ranging from several days to 2 weeks. The multiple baseline design protects validity of research by controlling for the effect of passage of time on the results (Slocum et al., 2022). We aim to randomise participants into multiple baselines, rather than selecting participants, to reduce the risk of researcher bias (Levin and Ferron, 2021).

The data collection schedule will remain the same as in Phase 3 (i.e. on 3 days per week, participants will receive 2-3 prompts to fill out a brief questionnaire, and once per week they will receive a prompt to complete a measure of headache-related disability and interference).

The personalisation will be an ongoing collaborative process. This means that the research team will revise the collected data each week, which will consequently inform each session's focus. Within PBT, the network map is viewed as always changing and therefore is revisited frequently during therapy (Ong et al. 2022). Within our study, we will use the network map as the preliminary case conceptualisation to identify key processes that might be contributing to headache-related disability. Consequently, we will collect weekly EMA data in between intervention sessions, and share this with participants to update the network diagram and to identify the key focus of the subsequent treatment sessions. The PBT network map, along with weekly intensive EMA data collection, during treatment and at follow-up, will help us to create a highly personalised, dynamic psychological intervention. The weekly EMA idiographic data will be reviewed with adolescents and will guide:

a) Network case formulation

a) Processes to focus on the personalised intervention

b) Decision-making on the overall course of treatment.

Data collection schedule: In line with recommendations arising from 24 EMA studies with adolescents, a "burst design" for data collection may be optimal to reduce participant burden (Heron et al, 2017). Participants will therefore have periods of breaks from data collection during each week. This has also been advised by EBEs who took part in trialling the data collection schedule. Compliance with questionnaire completion will also be measured.

Phase 5: Follow-up.

Following intervention completion, participants will continue completing daily questionnaires for a further 1-2 weeks, as well as weekly measures of headache-related disability and interference.

Study end. At the end of the follow-up period, participants will be contacted by email to inform them of the end of the study and to thank them for their participation. Additionally, we will offer an optional online debrief meeting to each participant.

Sample recruitment

The sample will be recruited from a specialist paediatric NHS service (initial discussions are currently ongoing). Clinical staff will identify participants by screening adolescents against the criteria and seeking verbal consent to pass their details to the research team to discuss study participation.

We aim to recruit an adolescent sample size of 12 (to allow for sample attrition) ranging in ages 12-18. We are aiming for a final sample of n=6 (i.e. number of participants who complete the study). This sample size is in line with other previous SCED studies with adolescents (e.g., Cawthorne et al., 2022; Sukhodolsky et al., 2013).

Table 1.

Inclusion and exclusion criteria for the study:

Inclusion	Exclusion
- Adolescents aged 12-18. - Recurrent headaches occurring for 3 months or more, ideally (but not necessary) diagnosed by a paediatric Neurologist (diagnosis of any idiopathic headache, using the International Classification of Headache Disorders criteria (ICHD-3 beta version). - The headache should be deemed to be resulting from a primary headache disorder as opposed to a secondary symptom of another health condition. - Currently **not** receiving psychological support elsewhere or have prior accengagement with psychological support for or due to headache for the past 6 months prior to screening. - Reporting PedMIDAS score of greater than 10 points (indicating at least minimal disability) - Adolescent and their caregiver fluent in speaking and writing in English - Frequent access to a smartphone and access to the internet whether public (e.g., library) or private (e.g., home, personal)	- Presence, history or suspicion of secondary headache disorder. - PedMIDAS of greater than 140 points (indicating excessive disability and need for multisystemic therapies). - Adolescent and their carer not fluent in speaking and writing in English. - Diagnosis of pervasive developmental disorder or serious mental condition (eg, psychosis, active suicide thoughts) as determined by the referral (either the parent/carer or the medical professional) - Adolescents living in families in distress (e.g., a family member experiencing another illness, mental health problem or psychosocial issues) - Limited access to a smartphone device with consistent internet connection. - Receiving psychological support elsewhere or have a prior engagement with psychological support for headaches up to 6 months prior to screening.

Assessment procedures

Demographics and clinical characteristics

Demographic information will be collected using Qualtrics between Phase 1 and 2. This will include the adolescent's age, gender, cultural background, headache diagnosis, headache profile (e.g., frequency, intensity, severity), and medication use.

Measures

Primary outcome measures

The primary outcome measures will be a series of Visual Analogue Scale (0-100) items that measure the following:

1. Perceived progress in a personally defined goal (1 item)

2. Perceived progress in ability to cope with headache (1 item)

3. Headache activity (frequency, duration, intensity and interference) (4 items)

Secondary outcome measures

Participants will respond once per week in a series of standardised measures, using a total of 2 questionnaires as outlined below.

1. **Headache interference.** The Patient Reported Outcomes Measurement Information System (PROMIS) Paediatric Pain Interference (PPI) Item Bank- 10 items (Varni et al. 2010) measures the daily interference of pain on physical, psychological, and social functioning. Higher scores indicate greater pain interference in the child's life. This is a unidimensional item bank (Varni et al., 2010), derived from a larger PROMIS item bank which has an overall good internal consistency (Cronbach's alpha= 0.98) (Cunningham et al. 2017) and convergent validity shown by significant correlations with other similar scales. The PPI scale has been validated in paediatric chronic pain samples (Ceniza-Bordallo et al., 2022).

2. **Measure of headache-related disability.** Headache-related disability will be measured using the Paediatric Migraine Disability Assessment Scale (PedMIDAS) (Hershey et al. 2001), which is a 6-item

questionnaire measuring the frequency of disruption to daily activities caused by headaches. This measure has been used in studies measuring headache related disability after pharmacological interventions (Powers et al., 2021). The PedMIDAS has been shown to have internal consistency (Cronbach's alpha 0.80) and validity in measuring headache-related disability (Hershey et al. 2001).

Other measures

Additionally, we will administer a Client Feedback Form at the final intervention session, based on Sekhon et al.'s (2018) theoretical framework of acceptability (TFA) for health interventions. This includes six items, rated on a 5-point Likert scale: affective attitude, burden, perceived effectiveness, intervention coherence, self-efficacy, and opportunity/ costs.

Statistical analyses

To address the first research question, we will analyse the weekly standardised data to assess change in disability (PedMIDAS) and headache interference (PROMIS) assessing reliable change (RC) and clinically significant change (CSC), using Jacobsen & Traux's formula (1991). (Scores will be compared against a calculated reliable change index, to indicate whether the level of change is statistically significant).

To address the second research question, we will examine change in personalised goal, headache activity (VAS items), and personalised processes of change (BPAT) across time. The longitudinal data will be plotted on a line graph to allow a visual analysis for patterns, trends and variability in the data (Dowdy et al., 2022). We will supplement the visual analyses with Tau-U statistical analyses to assess the proportion of overlap between phases.

We will additionally follow a tutorial by McDonald (2022) to conduct individual dynamic regression analyses using a time-lag model, using SPSS. We will develop models, based on periods of feedback provision (one per week- overall 5 tested models). For these analyses we will estimate the

autocorrelations with lag numbers representing previous data points (e.g., data from sessions 1-5 will be included). The lagged idiographic outcome variables (headache interference and activity) will be entered into the regression model along with predictor(s) (the BPAT items) to identify whether a significant relationship exists between the predictor and the outcome, while accounting for any autocorrelation.

Ethical considerations

This study will require ethical approval from the RHUL Ethics Committee and the NHS Research Ethics Committee. Research guidelines and principles of the BPS Code of Ethics and Conduct will be followed throughout the project. Several ethical issues arising from this research are detailed below:

Informed Consent

Informed consent will be sought from both the participant and their primary caregiver or parent. Consent will be obtained electronically and, and electronic signed copies of consent forms will be stored in a RHUL's databases, accessible only to the research team. Appropriate time will be given during enrolment to ensure that participants fully understand the purpose of the study and study requirements. Participants and their caregivers will be provided with an e-copy of the information sheet.

Participants and their caregivers will be made aware that their involvement with the study is fully voluntary and that they are able to withdraw from the study at any point without justification, which will not impact their reimbursement for participating. Participants will also be made aware that any data collected up until the point of withdrawal will be anonymised and retained for analysis, to protect the validity of the study.

It is unlikely that issues with capacity to consent will occur during the study.

Confidentiality

All the outcome measures will be collected using the mPath app and Qualtrics and stored as per privacy regulations on a secure server at RHUL. Participants will each be assigned a numerical identifier only known to the researcher throughout the study, to maintain confidentiality. Data will be fully anonymised when collected and writing the results of the study. All identifying information will be stored on a password-protected file which is only accessible by the research team. Consent and assent forms will be kept as per institutional policies and then shredded.

The adolescent's GP will be aware of the adolescent's participation in the study. The participant and their caregiver will be informed that any adverse effects occurring during treatment (e.g. suicidal or self-harm risk) will be reported back to their GP, as well as their caregiver if the participant is under 16. In case of less than imminent risk, then the researcher will encourage the participant to contact their GP/mental health provider. The research team will also encourage the participants to talk to trusted family members or other community support resources, and pass the subject contact information for the suicide hotline or similar crisis management organizations. In case of high imminent risk, the researcher would act quickly to protect the safety of the research participant. This means that the researcher will stay with the participant until assistance arrives or the person is transported to clinical care. Procedures for calling 999 to contact the nearest NHS Emergency department will be sought. The researcher will then notify and seek for support from the main supervisors.

Adolescents will be provided with an optional debrief meeting towards the end of the study, should they wish to do this.

Risk

It is possible that, while discussing difficulties in relation to headaches and taking part in psychological interventions, some themes of emotional distress may arise for the adolescents. For example, through completing EMA questionnaires adolescents may become increasingly aware of difficulties resulting from headaches. Contact details of ChildLine and Samaritans as sources of additional support will be provided on the participant information sheet and debrief sheet.

The research team (trainee and supervisor) will be available to contact via RHUL email throughout study participation, for any ad-hoc concerns that participants or caregivers wish to discuss.

As detailed in the above information regarding confidentiality, should participants indicate significant risk to themselves or others (e.g. self-harm, suicidal thoughts or intent), the participant's caregiver and health professional and/or GP will be made aware of this. This will be detailed in the consent form and study information sheet.

Data gathered from participants will be stored within mPath and Qualtrics. Participants will be assigned a numerical identifier only known to them and the researcher, to maintain confidentiality. Participants will be made aware of this when discussing consent to participate. The raw data will be stored by the researcher during the data analysis phase, and at this point will be deleted from the survey management tool.

In which aspects of the research process have you actively involved, or will you involve, patients, service users, or members of the public?

Please tick:

Design of the research *

Management of the research

Undertaking the research

Analysis of results

Dissemination of findings

None of the above

Details of EBE involvement

As advised by the REC at a previous NHS ethics submission, we have conducted a brief pilot with 2 experts by experience (EBE), recruited through internal networks. Each EBE will be reimbursed £50 for their contributions. The first EBE (female adolescent age 14) reviewed the information sheet and assent/consent forms to ensure age-appropriate language- we made amendments according to their feedback. The EBE then reviewed the measures to ensure that they were easy to understand, and completed a pilot of the data collection for 1 week. During this time period, they were sent prompts to complete questionnaires via Qualtrics throughout the day. Following this, a further meeting took place to discuss their feedback on the data collection, which was used to amend the study protocol. The EBE found the data collection at times repetitive, and therefore recommended at least 1 day break between data collection days. The EBE was also in favour of a prize-draw as an incentive for completing the study, rather than the initially planned £10 reimbursement per participant.

The second EBE (female, aged 14, diagnosed with migraine) completed a pilot of the intake assessment to ensure that this could be completed smoothly within the time limit. The overall feedback from the EBE was overall positive. The EBE valued an opportunity to talk about their experience and gain insight about their headaches. We further amended the intake assessment form, removing several questions which were deemed to be unnecessary for the case conceptualisation and/or repetitive.

Finally, we consulted further with adult and adolescent members of the public to review the participant information sheets and consent forms, to gather feedback about readability and accessibility of the information. The feedback was used to amend the participant-facing documents.

Practical considerations

The interventions used in the study will derive from already known CBT-based interventions. The trainee has experience in delivering low and high intensity CBT interventions and will receive clinical supervision from the lead project supervisor when delivering the interventions.

School-hours will need to be considered during weekday data collection, due to the likelihood that mobile device use may not be permitted at school.

In order to meet with participants and their caregivers, all the meetings will occur online.

Participants will be reimbursed for taking part in the project. In line with RHUL guidance, up to £10 in vouchers will be reimbursed to participants upon completion of the study. Should a participant or their caregiver wish to withdraw prior to study completion, they will nevertheless receive the reimbursement for participation.

Two participants who will act as experts by experience in the study will instead receive £50 each as a compensation for their additional contribution.

Dissemination

Participants will be provided with an option to receive feedback on the results of the study upon completion, by selecting this option on the initial consent form. The findings from the study will be presented to trainee clinical psychologists at RHUL as part of final year research presentations.

We will aim to submit the paper to a peer-reviewed journal such as the Journal of Pediatric Psychology (APA) or Behavioural Research and Therapy (BRAT).

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