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**Exploring Psychological Mechanisms of Change for Children and
Young People Utilising Ecological Momentary Assessment
(EMA): A Thesis Portfolio**

**Paper 1: Feasibility of ecological momentary assessment (EMA) for children and young people
with autism spectrum disorder: a systematic review**

&

**Paper 2: Exploring mentalization, the impact of trauma, and the mediation of perceived social
support on wellbeing in the daily life context of help-seeking trauma experienced young people
attending CAMHS: An Ecological Momentary Study**

School of Health in Social Science

DOCTORATE IN CLINICAL PSYCHOLOGY

University of Edinburgh

2024



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**School of Health in
Social Science**

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Acknowledgements

I would firstly like to extend my warmest thanks to Professor Schwannauer for his enthusiasm and guidance throughout the project. My greatest thanks should also be given to Dr Simona Di Folco, Dr Natalie Chalmers, Koraima Sotomayer, Islay Barne, Connie McKeand, Jordan Bibby and Sophie Houghton for their continued guidance and support within the research group. I valued our time working together and this would not have been possible without your collective input and support.

To Dr Gillian Radford and Dr Sara Shafi, thank you for providing such an open and welcoming space to learn and develop in a specialist trauma service for children and young people. Your insights and consistent support have been refreshing and I have always felt a genuine sense of curiosity with your supervision. I am also so thankful for the children and young people who agreed to take part in this research, as without them there would be no project.

To my wonderful family and friends who have encouraged me throughout my psychology career. You are there to celebrate every achievement, but I always know that you will be there when I experience setbacks along the way. Thank you for being always there.

Finally, I would like to express my deepest gratitude to my husband Craig who has always believed in me. You have been a constant source of strength, motivation, and peace for me throughout this doctoral journey. We have navigated so much together; a long-distance relationship, our wedding, buying our first house and getting our first pet together during the doctorate. You have helped me stay grounded and enjoy life amidst the unavoidable stress of this journey. I could not have done this without you, I am grateful for you daily.

Overall Thesis Abstract

Two research articles are presented in this thesis: a systematic review and an empirical project. The systematic review investigated the feasibility of using experience sampling methodology (ESM) with children and young people that have a diagnosis of autism spectrum disorder (ASD). Some children and young people with autism can face additional challenges, compared to neurotypical peers, contributing to poor outcomes. However, research can often rely on caregiver accounts of these difficulties, thus missing the opportunity to gauge the momentary child-reported fluctuations if self-reported. ESM allows for the measurement fluctuations within the context of one's everyday life, but to date, no review has explored this with children and young people with autism. As such, the review included 10 studies that utilised ESM with different recruitment strategies, participant training and ESM sampling and prompting design. Additionally, the studies explored different outcomes. The results indicated that there was significant variation in the quality of reporting of ESM studies. Overall, ESM was deemed a feasible methodology for gathering information on a young person with Autism's thoughts, feelings, emotions and behaviours within the context of their everyday life.

Secondly, an empirical research project investigated mentalization and the mediating role of perceived social support on the daily mental wellbeing of children and young people who reported experiencing traumatic events in their childhood. ESM methodology was used to measure all variables within this study. 27 participants completed 6 ESM assessments per day for 7 days. Results indicated that the momentary mentalization of others had a significant negative relation with momentary mental wellbeing. Moreover, momentary perceived social support was a significant predictor of momentary mental wellbeing and had a strong effect. The interaction of momentary perceived social support and average trauma impact was not significant. The interaction term for momentary perceived social support and momentary mentalization highlighted an additive effect. Lastly, structural equation models explored the mediation of average trauma impact and perceived social support on the relation between momentary mentalization and momentary mental wellbeing.

Lay Summary

Systematic Review

Exploring the thoughts, feelings, behaviours, and symptoms for individuals with autism spectrum disorder through research is key in informing interventions to help with key difficulties. However, at present, there is minimal research exploring these within the day-to-day experiences of individuals with autism. One research methodology, experience sampling methodology, asks participants to complete assessments several times a day over a planned study duration. This method has been used with a range of population groups (i.e., adults with and without an autism diagnosis, and children), with a growing literature base with children and young people with autism.

Some studies have raised potential barriers of using ESM with young people with ASD due to the significant range of cognitive (i.e., executive functioning and ability for set shifting, working memory) and social cognition. Ten studies were assessed to review if ESM was a feasible methodology for children with autism. The review showed that children with autism had compliance rates comparable to other reviews and completed assessments to a greater extent when assessments were less often and over a shorter study duration. Therefore, ESM was shown to be a feasible methodology when set up and designed appropriately to suit children and young people with autism.

Empirical Research Study

Adolescence is a key stage in life where significant changes occur biologically, socially, mentally. As such, this can be a vulnerable stage for the development of mental health difficulties. If young people also experience adverse childhood or traumatic events, there is an increased risk of further difficulties that impact their day-to-day life. Mentalization, being able to reflect on and understand your own and others mental states, is a key factor relevant to one's mental wellbeing. Mentalization is said to fluctuate depending on the context someone is in. Moreover, perceived peer support is said to play an important buffering role to contribute to more positive mental wellbeing. Research has also suggested that perceived social support varies depending on the context. As such, the study looks at the mentalization, perceived social support and mental wellbeing in the context of participant's day to day life using experience sampling methodology through an application on their personal smartphone. Young people will report on these factors by completing 6 short assessments per day over 7 days. The trauma impact will be explored via a checklist. 27 participants took part in the study. The results of this study showed that mentalization and perceived social support was associated with the day-to-day wellbeing. There was not an association found between the average trauma impact and perceived social support. Finally, the study found that perceived social support

mediated the relationship between mentalization and mental wellbeing. The study highlights the importance, and significance, of measuring these variables within the context of one's everyday life.

Chapter 1: Systematic Review



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**Feasibility of ecological momentary assessment (EMA) for children
and young people with autism spectrum disorder: A systematic
review, and further recommendations.**

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Word Count (excluding references): 11,723 words.

Author notes: No known conflicts of interest to disclose.

Written for submission to the British Journal of Clinical Psychology. See Appendix 11 for Author Guidelines.

Abstract

Objective: Research has demonstrated that experience sampling methodology (ESM) can be feasibly used with various population groups across the lifespan. Studies have reported the use of ESM with adults with autism to be feasible. However, to date, no systematic review has explored this with children and young people with autism, despite research suggesting that they can experience significant difficulties day to day that vary depending on the context in which they are in.

Method: The databases Embase, PsychINFO, MEDLINE were searched for relevant articles. A grey literature search was conducted via Social Science Research Network, ProQuest Dissertations and Google Scholar. The search terms used for the study included ESM OR EMA OR "experience sampling" OR "momentary assessment" OR "ecological momentary" AND ASD OR Autism OR "autism spectrum" OR Aspergers OR neurodevelopment* AND Adolescen* OR teen* OR "young people" OR "young person" OR youth OR "young adult" OR "childhood" OR "emerging adult" OR child.

Results: The review assessed 10 studies on their adherence to ESM reporting guidance and their feasibility was synthesised using a narrative approach. All 10 studies reported ESM as a feasible method for gathering contextual and momentary data for individuals with an autism diagnosis.

Conclusions: This study demonstrated that experience sampling is a feasible methodology for gathering contextually embedded assessments of children and young people with autism. However, tailoring the intervention to the sample of participants will aim to increase compliance and contribute to greater validity in results.

Keywords: *ecological momentary assessment, feasibility, young people, autism, systematic review,*

Practitioner Points:

- There is a current lack of studies utilising experience sampling with children and adolescents with autism.
- There is a lack of representation of females in samples included in the review due to studies not recruiting females or excluding females from their final sample due to small numbers which limited generalisability of the findings.
- Key aspects of the set up and design of ESM should be tailored to the needs of individuals with autism (i.e., the right balance of daily assessments, study duration, training and use of incentives) to increase feasibility.
- Experience sampling methodology is a feasible method of gathering assessments of young people with autism experience in the moment despite prior research raising concerns about its use.

Introduction

Mental Health of Children and Young People with Autism

Understanding and positively supporting the mental health of children and young people (CYP) with autism, through appropriate and meaningful assessment is a national and international priority (Toma et al., 2022). Autism spectrum disorder (ASD) is a neurodevelopmental disorder that is characterised by a range of features including challenges in social contexts, restricted interests, and stereotyped behaviours (APA, 2013). The Centre for Disease Control and Prevention (Maenner et al., 2023) reported that one in 36 children is diagnosed with autism spectrum disorder, and the diagnosis is reported to occur in all ethnic and socioeconomic groups. Consistently, prevalence rates for diagnoses of Autism are shown to be higher for males compared to females (Maenner et al., 2021). It has been proposed that there is a differential presentation of ASD in females compared to males (Tofani et al., 2023). For example, Hiller et al. (2014) showed that ASD diagnosed girls displayed less stereotyped use of objects and interests and were more likely to integrate verbal and non-verbal expressive behaviours, reciprocal conversations and share interests. Lai et al. (2020) reported that girls diagnosed at a young age were more likely to have better cognitive development, less severe symptoms and over time a reduction in symptoms. However, literature suggests that females were more able to recognise differences between themselves and atypical peers and subsequently camouflaged it by mirroring speech and behaviours of same-gendered peers (Gould., 2017). As such less pronounced cases in females are often not identified and therefore not diagnosed.

As the general prevalence rates of autism have increased over the last few decades, due to increased awareness and assessment, research has aimed to focus on understanding the needs of individuals with autism (Doda et al., 2024). However, understanding the needs can be challenging as individuals with ASD are not a homogenous group as each person can vary significantly in cognitive, fine motor skills and social skills (Kumm et al., 2021). Some children and young people with ASD often face challenges in participating in everyday activities, particularly social engagement and friendship development, compared to their typically developing peers (Cordier et al., 2016). As autism is multidimensional, young people with autism will likely have different needs and therefore require individual solutions and tailored interventions to help best meet these needs, especially as they transition

developmentally. For example, the two-hit mechanism model of ASD (Picci & Sherf, 2015) suggests that individuals with autism experience the first 'hit' or difficulty relating to their genetic and biological differences that predispose them to initial vulnerabilities and neurodevelopmental differences. The second 'hit' presents during the transition into adolescence where initial vulnerabilities become more exacerbated due to a myriad of changes and developmental tasks typical of adolescence including pubertal hormonal changes, social relationships, and academic tasks (Dallman et al., 2022). This model suggests that individuals with autism present with vulnerabilities that increase in weight as a young person transitions into adolescence and adulthood. These vulnerabilities can contribute to poor mental, physical, social, and functional outcomes. At present, the contributing factors to poor outcomes for CYP with autism are poorly understood as research can often rely on caregiver accounts, thus missing the opportunity to gauge the child-reported fluctuations that may differ from their caregivers' perspectives (Bangerter et al., 2019).

Assessment Methods

Within clinical practice and research, assessment techniques are varied depending on the focus of assessment. Traditional methods, such as static self-report questionnaires, interview schedules and observations have played an important and efficient role within assessment and research (Demetriou et al., 2015). Researchers have previously used single-occasion retrospective interview, global self-rating scales or caregiver reports to examine the subjective experience for individuals with autism (Chen et al., 2016; Trull and Ebner-Priemer, 2009). Traditional static measures can be subject to significant retrospective biases when participants have to aggregate experiences over time including recall bias, social desirability, personal heuristics effect, recency effect, novelty effect and mood-congruent memory effect (Trull et al., 2009; Tseng et al, 2023). To develop effective and ecologically valid research for individuals with autism, that reduce the discussed biases, there is a need to understand key mechanisms and their influence in the context of an individual's daily life (Chen et al., 2015). As such, increasing importance has been rightfully placed on understanding how an individual's self-reported symptoms, thoughts and behaviours fluctuate within the context of their daily life experiences. Measurement processes that are more contextually driven allow for more accurate representations of

participants' experiences and behaviours compared to traditional self-report measures. This can help with identifying the links between why and when behaviours occur, exploring changes over time and to understand the relationship between variables over time (Russell and Gajos, 2020).

Experience Sampling Methodology (ESM)

Experience sampling methodology (ESM) hopes to address some of the limitations of traditional methods of assessment and allow for a more informed understanding of the influence of contextual factors in an CYP's everyday life. Experience sampling methodology, also known as ecological momentary assessment, has been utilised with various population groups across the life span, as well as a multitude of different mental and physical health conditions (Bray et al., 2010; van Dalen et al., 2023). Experience sampling methodology has been shown to have many advantages for clinical psychology practice and research as a feasible and reliable method for studying the daily lives of youth as young as seven years old, as well as youth from different genders, ethnicity groups, nationalities, socioeconomic backgrounds, and mental/physical health difficulties (Russell and Gajos, 2022).

Utilising ESM offers researchers the opportunity to explore participants' fluctuations in their thoughts, feelings, and behaviours in their everyday life context (Chen et al., 2014). ESM data collection, in the real time context, offers a methodology to reduce the effect of recall bias, have more ecologically valid data of in the moment experiences and provides a rich dataset through less cognitively demanding assessment (Trull et al., 2009). Although traditionally completed using pen and paper materials, advancements and greater accessibility of technological devices (e.g., smartphones and tablets) have meant that ESM through digital means has become more commonplace (de Vries et al., 2021). This helps to mitigate against the traditional method's issue of 'back-filling' data during daily diary techniques as digitally formatted ESM can time stamp responses and can allocate time parameters for the completion of ESM observations. It has increased the ease of conducting research due it's ease for researchers and young people (Trull et al., 2009).

ESM with Children and Young People with Autism

Research has only begun to explore the use of ESM with children and young people with autism. Bakhtiara et al. (2021) examined 139 children and young people with autism aged between 8-17 years old and the validity of self-report questionnaires compared with typical peers. They found that children with autism can provide acceptable self-reporting, however they have greater validity issues compared to peers without autism (Bakhtiara et al., 2021). ESM could address some issues around validity by minimising memory biases or retrospective recall and maximising ecological validity (Myin-Germeys and Kuppens, 2022). William et al. (2020) conducted two studies aiming to quantify the degree to which ESM may be more accurate than retrospective self-report for momentary psychological data. Across both studies, they reported participants displayed a recall bias consistent with previous research showing a tendency for participants to recall greater negative affect than reported compared with real time. They suggested that having information about the exact timing of mental states is critical and that retrospective accounts that rely on memory of momentary mental states would not be sufficient (William et al., 2020).

Moreover, ESM is proposed to be a methodology suited to capturing the inherent variability within the ASD population across contexts (Chen et al., 2015; Hare et al., 2020). ESM question schedules are designed to be short, straightforward, and address only the necessary immediate contextual information, which involves less cognitive demand than traditional retrospective methods (Chen et al., 2015). As Autism is not a homogeneous diagnosis - due to individual variabilities in cognitive, motor and social skills - it could be suggested that developing ESM research and clinical tools to meet the wide range of differences and parameters that change per person could be challenging (i.e., reading level; Nally et al., 2018). Additionally, research queried the willingness of participants to interrupt their current activity to complete a prompted ESM observation given the belief that CYP with ASD often struggle to shift their attention and resist change in their daily routines often called set shifting (Chen et al., 2014; Yerys et al., 2009). It could be suggested that children and young people with ASD may require additional motivational assistance following prompting (Chen et al., 2015). However, studies have shown somewhat comparable response rates to neurotypical individuals (Chen et al., 2023).

Random-sampling strategies used within ESM (i.e., randomly signalled ESM beeps across assessment duration) would not offer a predictable and consistent methodology for participants, which is often preferred for individuals with autism (Goris et al., 2020). This may contribute to poorer compliance rate and attrition meaning data becomes invalid, unreliable and conclusions are unable to be drawn to inform research and practice. Further difficulties may include being able to reflect on their thoughts, feelings and behaviours in the moment (Chen et al., 2014). ESM research with adults with ASD found that drawings depicting internal experiences (e.g., facial expressions) are more suitable than a written format for reflecting on social experiences. Chen et al. (2015) also reported that formatting questions as a slider or with a dichotomous answer was deemed more suitable.

As such, it is evident that the use of ESM is suggested to require additional considerations when using this methodology with children and young people with autism. However, due to the limited evidence available, these considerations and the feasibility of this ESM with CYP with autism with various ranges of abilities remain unclear.

Rationale for Systematic Review

As far as the researchers were aware, there is no current review of the feasibility of utilising ESM with children and young people with autism directly. Many previous studies explore the feasibility of utilising this methodology with caregivers or staff, and do not measure the young persons' subjective experiences (Bangerter et al., 2019; Wallisch et al., 2023).

Research has suggested potential difficulties with utilising ESM with children and young people with ASD. Research suggested that ESM could pose difficulties for children and young people with ASD due to the requirement to independently manage shifts from their daily routine or tasks or interests. Furthermore, ESM often is designed to offer inconsistent and unpredictable prompting which may attending to ESM beeps more burdensome. Other difficulties may include difficulties for young people with Autism in firstly identifying, and then describing one's own feelings on a momentary basis. As such, ESM may pose feasibility issues for children and young people with autism based on the variation of needs and preferences within such a heterogeneous group. Considerations of the needs of

children and young people with ASD during the designing of ESM studies is essential to reduce barriers and improve feasibility.

A greater understanding of the usability and feasibility of utilising ESM with CYP with Autism directly would help steer further research in the area. The present systematic review aims to systematically synthesise the methodological characteristics of the included papers to assess whether ESM is a feasible methodology to use for children and young people with Autism independently and to highlight key considerations for researchers planning to use ESM with children and young people with autism.

Methods

Design

The Preferred Reporting Items for Systematic Reviews and Meta-Analyses Statement (PRISMA; Moher et al., 2009) informed how the review was conducted. The protocol was registered in the international prospective register of systematic reviews, PROSPERO registration number CRD42024491768.

Inclusion & Exclusion Criteria

Studies were included in the present study if they used intensive longitudinal methodology such as experience sampling methodology (ESM) or ecological momentary assessment (EMA) to explore any phenomena relevant to mental health including cognitions (thoughts/perceptions), affect, behaviours and experiences (e.g., coping or activity) for children and young people with Autism. The studies must involve a child and/or young person population with a diagnosis of Autism. The World Health Organisation (2003) defined the adolescent age category to include those aged 10-19 years old. However, due to the often-delayed timing of role transitions (e.g., completing education, marriage, and parenthood), it has been proposed that the age category is to be extended up to 24 years of age (Sawyer et al., 2018). As such, the current review incorporates studies with participants up to this age range to encapsulate children and young people within a more updated operationalisation. Only studies published in English were included, but there was no geographical or date of publication exclusions applied. Unpublished dissertations were

considered for this review. Exclusions included protocols of studies, systematic reviews or meta-analyses. Moreover, studies were not included if the participants' caregivers were completing the ESM assessments.

Search Strategy

PsychINFO, MEDLINE and Embase databases were used to search for articles based on the inclusion and exclusion criteria. In addition, a grey literature search via Social Science Research Network (<https://www.ssrn.com/index.cfm/en/>) and Google Scholar was conducted to minimise publication bias and include as much relevant evidence as possible as recommended by the Cochrane Handbook (Higgins et al, 2023). One article was sourced from a grey literature search. Furthermore, reference lists of articles were also screened by the lead researcher to ensure the search strategy was as extensive as possible, but no additional studies were identified through this method. The database search had three search sets and were linked with the term "AND". In addition, each individual search term was linked using the word "OR". For some words, a wildcard asterisk was used to ensure related terms were gathered during the search (i.e., adolescent was adolescen*). The search included the following terms:

- 1) ESM or EMA or "experience sampling" or "momentary assessment" or "ecological momentary"
- 2) ASD or Autism or "autism spectrum" or Aspergers or neurodevelopment*
- 3) Adolescen* or teen* or "young people" or "young person" or youth or "young adult" or "childhood" or "emerging adult" or child

Study Selection

Covidence systematic review software was utilised for this review. Studies were transferred into Covidence, and duplicates were automatically removed. The primary and secondary reviewers screened 100% of study titles and abstracts according to the written description of the inclusion and exclusion criteria. The screened articles were then categorised into either 'Yes', 'No' or 'Maybe' relating to eligibility for inclusion. For articles that were categorised as 'Maybe', or where there was a disagreement in categorisation, both primary and secondary reviewers discussed to resolve and to come to an agreed discussion. Full texts were then reviewed and categorised again, being divided into 'eligible for inclusion' or

‘ineligible’ for inclusion to the review. Disagreements were resolved between the two researchers by each discussing how these studies did or did not meet the criteria and evidencing this within the paper’s text. Three studies were discussed and excluded due to the wrong population being included and an incorrect age range according to the inclusion criteria.

Quality Assessment

Despite an increase in popularity and prevalence of research being conducted using experience sampling methodology, to the best of our knowledge, there are no approved or standardised tools for the quality assessment of ESM studies. Other quality measures were deemed unsuitable as many are designed to assess specific research study designs or for evaluating randomised controlled trials (e.g., Cochrane Risk of Bias 2.0 tool; Sterne et al., 2019). Quality was assessed for each study using an existing checklist for EMA studies. The adapted version of the Checklist for Reporting of EMA Studies (CREMAS; Liao et al., 2016) was derived from an adapted ‘Strengthening of the Reporting of Observational Studies in Epidemiology (STROBE; von Elm et al., 2008). Within the ESM systematic review base, the CREMAS has been used consistently to assess study quality however it is important to note that the CREMAS is a guideline for reporting of ESM studies, and not a quality assessment protocol (Logullo et al., 2020; Molsa et al., 2022).

The adapted CREMAS identified 16 items to be assessed to understand a study’s quality of reporting of the use of ESM and its features including the study’s title, rationale, participant training to use ESM, technology utilised (i.e., smartphone and app), wave duration (i.e., one or more assessment period), monitoring period (the days of each data collection period, and whether weekday or weekend), prompting design (i.e., interval based: fixed, random or event-based), prompt frequency (number of prompts per day), design features to address potential sources of bias, attrition by monitoring days and waves where appropriate, prompt delivery (how many assessments were planned to be delivered vs actually delivered), latency (the time between prompt signal and the answering of the prompt), compliance rate across all of sample and individual participants, missing ESM data, limitations and conclusions. The extent to which the included studies fully met, partially met, or did not meet the criteria outlined in the adapted STROBE CREMAS is reported

qualitatively, along with a descriptive summary of the range of reporting practices. An additional category for assessment regarding feasibility indicators was included considering the intended research question. A second researcher assessed the adherence to guidelines for 40% of the included papers, of which there were no disagreements on ratings. Studies were scored according to the following coding: green indicating the guideline was met scored 1, amber indicating the guideline was partially met scored 0.5, and red indicating that the study did not meet the guideline scored 0. Studies could gain a total score of 17 if all guideline criteria were met. See Table 3 for quality assessment.

Data Analysis

A narrative synthesis approach was utilised as the outcome of the review was to assess the feasibility of using ESM with children and young people with Autism. Feasibility was assessed by reviewing the studies capacity to recruit participants with Autism, to train participants to use ESM, and in relation to studies attrition to the study and compliance to ESM beeps across the assessment period. The requirement for specific adaptations and the ability to derive meaning from results of included articles will also be observed to understand feasibility.

Results

Study Selection

One hundred and twenty-two articles were identified through a database search. One additional article was sourced out with of the database search. Two duplicates were removed automatically by the Covidence software. One hundred and twenty-one titles and abstracts were screened against the inclusion and exclusion criteria, of which 99 articles were excluded following 100% of full articles being reviewed by 1st and 2nd reviewers. Some screened studies included participant samples above the required age inclusion criteria (i.e., age range up to 30 or 45 years old). Unfortunately, none of these studies broke these ages in categories and so were excluded from the review. Three full texts could not be accessed for review and were therefore excluded from the final review. Nineteen full texts were screened for eligibility, of which 9 texts were excluded for exceeding the inclusion age range and/or including the wrong population. For example, one paper's participant sample had

confirmed an intellectual disability diagnosis but did not report participants of also having an autism diagnosis. One article was also a systematic review. Ten articles were included in the final review. A full breakdown of study selection phase is documented in a PRISMA flow diagram (Figure 1).

Study Sample Characteristics

There were 10 studies included in this review within the publishing range of 2011 to 2023. These studies utilised samples from both a clinical and non-clinical population. Four out of the 10 studies compared individuals with autism with a control group of neurotypically developing individuals. Participants ranged in age from 8 to 19 years old ($M = 13.37$ years old). The study sample sized ranged from 6 to 133 participants. Studies were from a range of geographic areas including Australia, Taiwan, and the USA. See Table 1 for a further breakdown of the sample and purpose of the included studies.

Study Technical and Design Characteristics of ESM

As shown in Table 2, the studies included in this review have a range of ESM technical and design characteristics. These methodological characteristics are utilised as feasibility indicators for this review. Some studies were primarily ESM feasibility studies, whereas others had other primary research aims. There were varied approaches to how researchers gathered data from participants. For example, some utilised developed ESM apps that automate ESM observations whilst others used text or phone call prompts to remind participants to complete questionnaires via survey platforms. The study observations frequencies (i.e., beeps) ranged from 4 to 7 assessments per day and study duration ranged from 4 to 14 days.

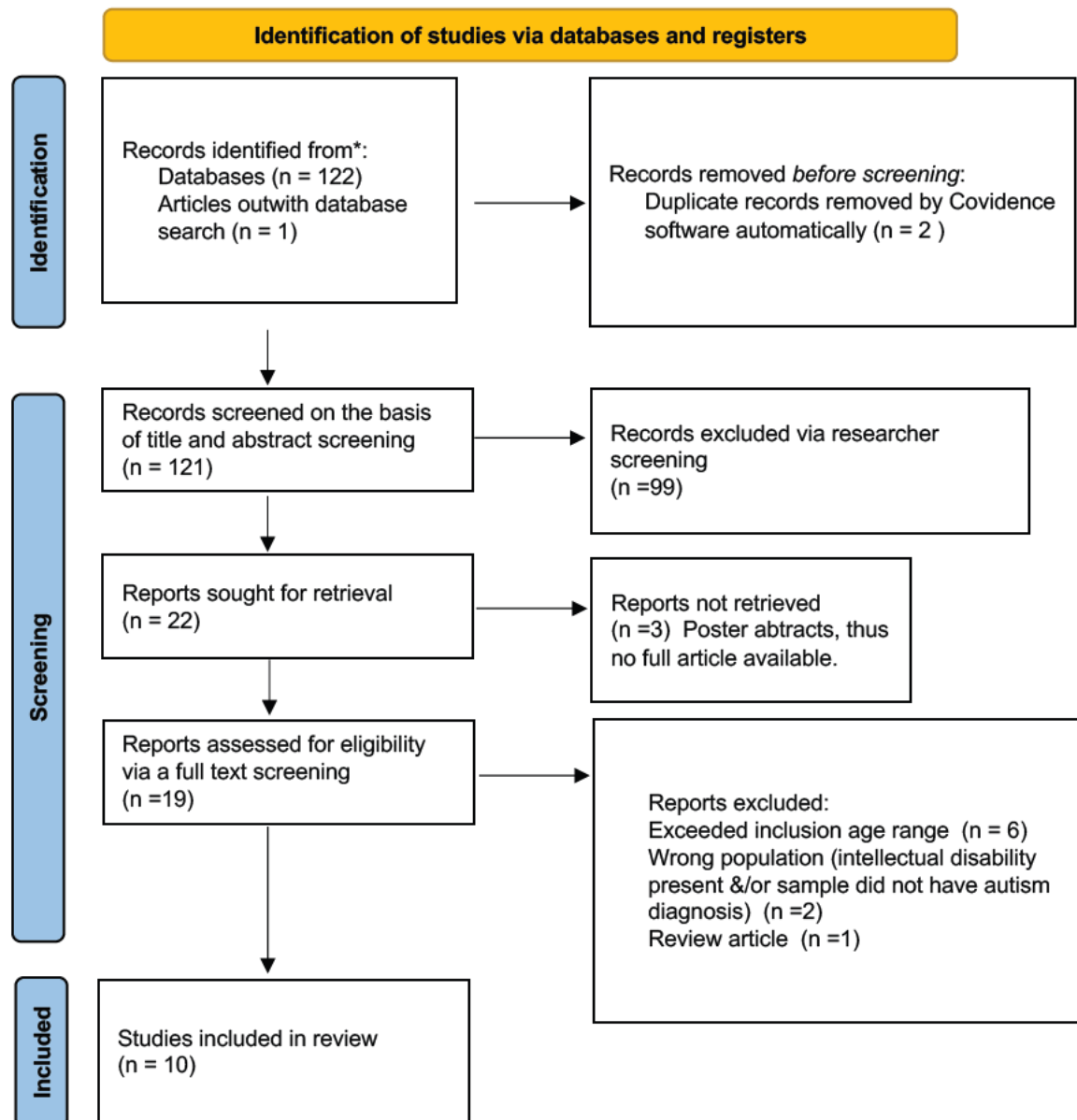


Figure 1: PRISMA Flow Diagram

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372: n71. doi: 10.1136/bmj. n71

Table 1
Summary of Sample and Purpose of Included Studies

Author (Year)	Country	Study Title	Sample					Primary Outcome Measure	Limitations of study & Future Recommendations
			Autism diagnosis confirmation	N	% Male	Age Range Mean (S.D)	Control Group		
Chen, et al., (2015)	Townsville, Australia	A preliminary study on the reliability and validity of using ESM in children with ASD	Formal diagnosis of either ASD or high functioning autism made by psychiatrist or paediatrician.	6	100%	8-12 yo M= 10.7 (SD 1.1)	NO	Feasibility of ESM	-Dichotomous response answers or less options on slider scale preferred -CYP should be prompted to bring their ESM device to help compliance -Teachers within school to be made aware of study so YP can complete during school hours. - Motivational assistance needed via encouragement/ prompting.
Chen et al. (2023)	Taiwan	The impact of coping behaviours on perceived competence and social anxiety in the everyday social engagement of autistic adolescents	Formal diagnosis by a psychiatrist of ASD according to the DSM-IV-TR or DSM-V.	133 total: A: 82 NT: 51	A: 90.2% NT: 35.3%	10-16 yo M= 12.5 (SD 2.1)	YES	Perceived competence and social anxiety	-Extending the duration of ESM observations as often YP with autism were not interacting socially (longer duration may help gather data on naturalistic social situations.
Cordier, et al., (2016)	Queensland Australia	Piloting the use of experience sampling method to investigate the everyday social experiences of children with Asperger syndrome/high functioning autism	Had a formal diagnosis of AS or HFA made by psychiatrist or paediatrician, (b) had an Autism Diagnosis Observation Schedule (ADOS) screening at the time of diagnosis,	6	100%	8-12 yo M= 10.7 (SD = 1.1)	NO	Social experiences	Small, uncontrolled sample – caution should be applied when interpreting the findings – limits ability to generalise findings.
Dallman, A.R (2020)	North Carolina, USA	Understanding the Affective Dimension of Occupational Participation among Adolescents with Autism Spectrum Disorder: An Ecological Momentary Assessment Study	Diagnoses confirmed through parent-report and by research registry who verified participants met cutoff scores on the ADOS-2.	17	100%	11-17 yo M= 14 (SD= 2)	NO	Depressive symptomatology and subjective experiences of occupational participation for adolescents with ASD	Some ESM questions did not allow participants to report a broader category. 6 beeps per day – could not examine a cross-section of emotional experiences

Dallman, et al., (2022)	North Carolina, USA	Identifying predictors of Momentary negative affect and depression severity in adolescents with Autism – ESM study	Confirmed clinical diagnosis of ASD	17	100% Researchers excluded females due to small sample size.	11-17 yo M=14 (SD 2)	NO	Momentary negative affect and depression severity	-Females excluded from study, and use of mobile phone requires sufficient economic resources – results cannot be interpreted as describing the full population. -No formal diagnostic criteria administered to confirm diagnosis (although referrals were from registry where diagnosis is required). - No control groups
Khoret al., (2014a)	Victoria, Australia	Feasibility and validity of ecological momentary assessment in adolescents with high-functioning autism and Asperger's disorder	Met DSM-IV criteria for Autism or Asperger's disorder- confirmed through case review of diagnostic reports & response to Social Communication Questionnaire.	32	83.8%	12-18 yo M= 14.46 (SD 1.83)	NO	Feasibility and validity of ESM	Small sample size Lower than optimal compliance rate may data does not accurately reflect participants' experience. Unclear whether EMA reports were sufficiently brief to enable an accurate account of experience. EMA asked participants to recall stressors – may still be subject to recall bias.
Khor et al., (2014b)	Victoria, Australia	Coping, daily hassles and behaviour and emotional problems in adolescents with high-functioning autism/Asperger's disorder	Met DSM-IV criteria for ASD or Aspergers. Cases confirmed via a case review of diagnostic assessments.	31	84%	12-18 yo M=14.46 years, (SD=1.83)	NO	Behaviour and emotional problems	Small sample – limits generalisation to broader population Adolescents were asked to report on hassles/coping that had occurred since the last signal which does not truly mitigate against biases present in other methodologies. Did not complete beeps during school, thus missing out on conceptual information important to age range/population.

Kovac, (2015)	North Carolina, USA	Affect-modulated Postauricular Reflexes of Children with Autism Spectrum Disorder To examine affective responses to social and non-social stimuli in children with ASD	Confirmed by score above threshold for ASD on the Autism Diagnostic Observation Schedule (ADOS-G).	39 A: 19 NT: 20	A: 74% NT: 80%	9-18 yo A: M=14.11 (SD 3.33) NT: M=14.5, (SD 1.96)	YES	Postauricular reflex (PAR) - response sensitive to affect.	-Small sample size and small number of EMA observations – thus results regarded as exploratory for EMA. -Children with cognitive impairment excluded from study, thus limited to a limited subset of children with ASD -Unable to ascertain if beeps filled in right away or at a later time.
Kovac et al., (2016)	North Carolina, USA	Experience sampling of positive affect in adolescents with autism: Feasibility and preliminary findings	Diagnoses confirmed through an ADOS administered by trained research staff.	A: 19 NT: 20	A: 74% NT: 80%	9-19 yo A: 14.11 (SD=3.3) NT: 14.5 (SD=2.0)	YES	Feasibility of ESM, measuring positive affect	Small sample size, and only 'high functioning autism' included in the study. Study does not address comorbidities present. Only 6 contacts per day over 4 days - small number of ESM observations; thus, may not be representative.
Rump, (2011)	Pittsburgh, USA	Affective experiences in adolescents with autism: An EMA study.	ADOS, autism diagnostic interview- revised administered with the young person. The Autism Diagnostic Interview- Revised was administered with parent.	A: 19 NT: 19	84.2%	11-17 yo A: M=14.68, (SD=1.93) NT: M=14.11, (SD=1.6).	YES	Affective awareness	Small sample size with limited power – could not allow for exploration at the subgroup level. Selection bias as likely that only those comfortable talking on the phone took part in the study – data not representative of those who find it most difficult reporting their difficulties. Calls only occurring out with of school limit understanding of affect in these contexts. No investigation of missed calls.

*Note: A= Autistic/ Aspergers, NT = Neurotypical

Table 2
ESM Design and Feasibility Indicators for Included Studies

Author (Year)	ESM Device	Prompt Design	EMA Beeps	Study duration	# of ESM Items	Recruitment	Training	Attrition	Compliance	Incentive	Study Self-Reported Feasibility
Chen et al., (2015)	ESM survey application (P.I.E.L Survey) for iOS devices Provided iPod touch.	Random sampling - had to start the survey 2 minutes after prompting. 7 days 2-minute window to answer beep	7 beeps/day	7 days (after 3 days of practice and a 3-day rest)	22 items	Convenience sampling - recruited through special interest group of occupational therapists in paediatrics.	Demonstration of using the iPod touch, accessing the PApp and instructions on completing the survey. Followed by 3-day trial. Youth and Caregiver	NR	Average signal response rate 56.8% (range 41 to 76%) Mean time completing = 1 min 53s (SD, 18s)	NR	Feasibility study deemed ESM feasible for use with CYP with autism. Data was reliable & valid. Participants reported difficulty transitioning if playing computer games as they would try to ignore prompts.
Chen et al. (2023)	Mobile device Using the 'participation in everyday life survey application (P.I.E.L App) designed for iOS device.	Random sampling times during waking hours 2-minute window to answer beep	7 beeps/day	7 days	NR	Recruited via research flyers distributed through autism-related organisations/ groups/school/ clinics and on social media.	Up to 60-minute training session (installation of app & instructions for app) Youth and Caregiver	NR	Required to complete at least 17 or 49 surveys (>33%) over 7 days. All compliance = 37/ 49 surveys (M=76.5%, SD=15.6%, range 34.7%-100%) A: 36/49 beeps (M = 74.1%, SD = 14.9%, range = 34.7%–100.0%). NT: 39/49 (M = 80.4%, SD = 13.8%, range = 36.7%–100.0%).	NR	Deemed feasible for 'intellectually able' CYP with ASD.

Cordier et al., (2016)	iPod touch, signalled to complete short survey on P.I.E.L app. Provided iPod touch	Random sampling during waking hours Had to respond to survey within 3 minutes, and complete in 5 minutes.	7 beeps/day	7 days	22 items	Recruited through Paediatric special interest group.	Training on the use of ESM: how to use the iPod touch, access & navigate the survey. Survey to check understanding. then young people completed a 3-day data trial. Youth and Caregiver	NR	The participants completed more than 27 surveys on average (range: 20–37 surveys). The overall signal response rate of participants was 56.8% (range: 41–76%). M completion time: 1m 44s (SD= 1m 2s)	NR	Feasibility pilot study deemed ESM feasible and able to capture information for CYP with autism.
Dallman, (2020)	Signalled via message to complete questionnaire through Qualtrics on mobile phone	Semi-random sampling First beep random, and subsequent EMA signals not randomised. No time limit to respond to survey.	6 beeps/day	7 days	15 items	Recruited through ASD research registry, flyers on social media and a central database of university affiliates.	Training in how to complete EMA and were asked questions to clarify understanding. Youth only	NR	Participants (n=12, 71%) completed at least 60% of the EMA procedures. Five participants were below the 60% threshold with the lowest response rate was only seven times (i.e., once per day). M completion time: 59s (SD =42S)	Participant contingent compensation on (compensation based on the number of responses completed)	Deemed feasible methodology. -used visual adaptations for some ESM items.
Dallman et al. (2022)	Mobile assessment questionnaire sent via text message link.	Semi-random prompting within 2hrs of parent-reported wake time, then 2 hrs	6 beeps/day	7 days over a child's 'typical week (i.e., not travelling)	NR	Recruited via referral through university affiliated institutions that support individuals with autism and flyers on social media.	Completed practice EMA procedure prior to the start of EMA protocol. Youth only	Of the 42 agreed to take part, 3 people withdrew before	Mean number of surveys completed out of 42: 31.53 (9.73)	NR	ESM deemed feasible for CYP with autism with an IQ above 85.

	-One participant excluded for not having a mobile phone.	after this prompt Time to answer prompt not reported.						doing any surveys	Mean= 75.1% compliance		
Khor et al., (2014a)	'Mobilitytype' program, mobile phone application comprising four modules of questions adapted from previous mobile type studies. Study lent out mobile phones to participants with the application downloaded.	Semi random sampling Random times one within each of four stratified intervals in both weekday and weekend blocks Sent by text. message at random times -once within each stratified interval. Time to answer prompt not reported.	4 beeps/day	14 days	NR	Letters, flyers sent via schools, ASD support networks and a centre database of eligible participants from previous research who consented to further contact.	Completed practice entry with researcher and explanation of use the mobile program. Youth and Caregiver	1 excluded during analysis due to having intellectual disability	Moderate compliance 61.81% (SD= 29.98%) Mean completion time not reported.	\$20 telephone credit as partial reimbursement for their time.	Feasibility study deemed feasible for CYP with high functioning ASD. Mixed compliance rates, but less feasible/ lower compliance for CYP with lower IQ
Khor et al., (2014b)	Mobile phone – 'mobile type' program, 4 modules of questions By text message prompting sent at random times – once within each of 4	Semi-random within each of four stratified intervals Time to answer prompt not reported.	4 beeps/day For weekdays, the blocks were 7.30–8.30a.m., 5–6.20 p.m., 6.20–7.40 p.m.,	14 days	NR	Letters, flyers sent via schools, ASD support networks and a centre database of eligible participants from previous research who consented to further contact.	Tutorial of using EMA tool provided including completion of practice entry. Youth and Caregiver	NR	M= 2.65 completions per day, SD =1, M= 66.3% Mean completion time not reported.	NR	Deemed feasible for CYP with high functioning ASD

	stratified intervals. Study lent out mobile phones to participants with the application downloaded.		7.40–9.00 p.m. For weekends, the blocks were 9 a.m. to 12 p.m., 12–3 p.m., 3–6 p.m., 6–9 p.m.								
Kovac (2015)	Electronic questionnaire – prompt and link delivered via text and email	Report as automated, but no further detail. Time to answer prompt not reported.	6 beeps/day	4 days: Friday afternoon, two on Saturday and two on Sunday	NR	Recruited using the UNC Autism Research registry	Administration overview - shown screenshots of what the message prompts and mood check would look like. Youth and Caregiver	One survey was deemed unusable because it had been filled out by a caregiver and was excluded from further analysis.	High compliance: 90% response rate (94% among controls, and 85% among participants with ASD) One survey unusable as completed by caregiver. Mean completion time not reported.	NR	Deemed feasible and viable method for CYP with autism. -adapted questions to have less complex language and to have visual supports.
Kovac et al., (2016)	Text message prompt with web link to Qualtrics survey platform. If no access to texting, phone calls would occur (2 participants).	Pseudo-random sampling strategy Time to answer prompt not reported.	6 beeps/day One on Friday, two each day of weekend and one on Monday	4 days	NR	Recruited the Autism subject registry	Administration overview – shown screenshots of what text message prompt would look like that and completed a practice administration with support from research staff. Youth & Caregiver	3 participants withdrew before completing any measures	89% overall response rate. The ASD group completed 97/114 (85%) of the assessments and the control group complete 111/120 (93%) of the assessments, a significant difference (t-test comparing proportions = 2.19, p=0.024).	NR	Feasibility study deemed feasible with CYP with high functioning ASD.

-Mean
completion time
not reported.

Rump (2011)	Participants provided with an 'answer-only' mobile phone. Telephone call format. If did not answer on first attempt, 2 nd phone call attempt occurred after around 10 minutes. 3 rd attempt made 10 minutes after 2 nd attempt.	Semi random within specified time blocks. Mean completion time not reported.	Weekdays : 2 calls/day, between 4-7pm and 7:01-10pm) Weekend s: five calls/day, between 10:00am and 10:00m	14 days	21 items during the day 25 items on last call of the day	Recruited via an autism centre for excellence	EMA procedure explained to youth and caregiver, demonstration of how to use equipment. Mock call to familiarise participant with format & questions of interview. Youth and Caregiver	Fewer than 60% of calls completed = non-completers. One participant with autism, answered 29 calls, but did not provide responses for last 14 calls and so was excluded. One control group participant = non-completer.	Compliance rate for both the autism and control groups was 78%, respectively, with participants completing an average of 31 of 40 calls. Autism group: SD = 4.2, Range: 24-39 Control group: SD = 4.6 Range: 22-37).	NR	Deemed feasible methodology with CYP with high functioning autism. -some participants struggled with phone calls so may not represent those with greatest difficulties as they were unwilling to participate.
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Note: NR = not reported, CD = cannot determine.

Table 3*Adapted STROBE Checklist for Reporting of EMA Studies (CREMAS; Liao et al., 2016)*

	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	Q
Chen et al (2023)	Amber	Green	Green	Green	Green	Green	Green	Green	Amber	Red	Green	Green	Green	Red	Green	Green	Green	14
Chen et al (2015)	Green	Green	Green	Green	Green	Green	Green	Green	Amber	Red	Red	Green	Green	Green	Green	Green	Green	14.5
Cordier et al (2016)	Green	Green	Green	Green	Green	Green	Green	Green	Green	Red	Red	Green	Green	Red	Green	Green	Green	14
Dallman (2020)	Green	Green	Green	Amber	Green	Green	Green	Green	Green	Amber	Green	Amber	Green	Green	Green	Green	Amber	15
Dallman et al (2022)	Green	Green	Green	Amber	Green	Green	Green	Green	Green	Amber	Green	Red	Green	Green	Green	Green	Amber	14.5
Khor et al (2014a)	Green	Green	Green	Green	Green	Green	Green	Green	Red	Green	Red	Red	Green	Green	Green	Green	Green	14
Khor et al (2014b)	Red	Green	Green	Green	Green	Green	Green	Green	Amber	Red	Red	Red	Amber	Red	Green	Green	Amber	10.5
Kovac (2015)	Red	Green	Green	Green	Green	Green	Green	Green	Amber	Amber	Green	Red	Green	Amber	Green	Green	Green	13.5
Kovac et al (2016)	Green	Green	Green	Green	Green	Green	Green	Green	Amber	Red	Green	Red	Green	Amber	Green	Green	Green	14
Rump (2011)	Green	Green	Green	Amber	Green	Green	Green	Green	Amber	Green	Green	Red	Green	Green	Green	Green	Green	15

**** Note:** Q= quality score, maximum score of 17.**Green = fully met (scored 1), Amber = partially met (scored 0.5), Red= not met at all (scored 0)**

1. Title & Keywords 2. Rationale 3. Training 4. Technology 5. Duration 6. Monitoring Period 7. Prompting Design

8. Prompt Frequency 9. Design Features 10. Attrition 11. Prompt Delivery 12. Latency 13. Compliance Rate

14. Missing Data 15. Limitations 16. Conclusions 17. Additional item: ESM Deemed Feasible.

Q= Quality score, maximum score of 17.

Results

Quality Assessment based adherence to CREMAS Guidelines

As shown in Table 3, despite the production of the adapted STROBE Checklist for EMA Studies (CREMAS), the methodological reporting of ESM studies varies considerably across research study design and methodological reporting. It is crucial that studies are transparent and clear with their design and methodology to improve the research integrity and reproducibility of the studies (Prager et al., 2019). The included studies ranged in their adherence to guidelines, scoring from 10.5 to 15 out of 17 (M= 13.9). In all 10 studies, it was indicated that ESM was a feasible methodology for use with children and young people with autism where data was valid and used for analysis (see feasibility section for further expansion). Key areas for further development within the ESM research base identified from the CREMAS include reporting of ESM design features, attrition, prompt delivery, latency, and missing data.

Reporting the participant attrition throughout the study, such as by monitoring days was poorly adhered to with 50% (N=5) of the included studies (Chen et al., 2015; 2023; Cordier et al., 2016, Khor et al., 2014b; Kovac et al., 2016). Studies were able to report overall attrition for most cases, but no studies indicated the attrition rate per day of the research study. The prompt delivery item on the checklist, suggests that studies should report the number of planned ESM prompts and how many were received by the participants. If any ESM items were not received by participants, explanations for this should be provided. Studies were typically clear with reporting the number of total beeps in the prompting design, but the number of studies that reported received and or reasons for technological difficulties was not provided for 40% (N=4) of the studies. Latency, the time difference between a prompt and a participant's response, was not reported in 60% (N=6) of the studies included in the review. The reporting of latency is important as ESM research is meant to capture the in-the-moment response from participants. One way to help improve the latency of responses is to set up time parameters for completing the beep. Whilst some studies reported whether missing data was in relation to time-variant of demographic considerations, this was not completed at all for 30% (N=3) of studies, and only partially completed for 20% (N=2) of studies. Missing data within ESM should be investigated for systematic associations with known temporal (time of day, day of week, day of study duration, study wave) and demographic (i.e., age, gender) factors (Liao et al, 2016).

Overall, the general adherence to the CREMAS guidelines was fairly moderate across the studies but further improvement in adherence would strengthen the scientific impact and possible use of findings for ESM studies (Liao et al., 2016). Some of the categories that have not been adhered to fully could be explained for several reasons, such as journal word count being too limited to provide detail on all the desired items in the checklist. A poor study design could also explain the findings, although the guideline was published after the publication of 70% of the included studies.

Synthesis of ESM Characteristics of Included Studies

Topic 1: ESM Implementation: Key Feasibility Indicators

1.1 Recruitment

All 10 studies utilised convenience sampling methodology to recruit young people with autism spectrum disorder for the study. Researchers typically adopted more than one method of recruiting participants. The two most common recruitment strategies were through special interest groups (i.e., paediatric special interest group), centres or organisations (N=5) and through autism related databases or registries (N=5). Registries included the Autism Subject Registry, ASD Research Registry and the UNC Autism Research Registry. Databases included databases of eligible participants from previous research that consented to be contacted for further research, and a central database of university affiliates that support individuals with autism. Following this, studies utilised flyers distributed through autism-related organisations, groups, schools, and clinics. Three (N=3) studies utilised social media to distribute flyers. Trull and Ebner-Priemer (2020) suggest in their guidelines that the participant sample should not be chosen purely for convenience, and that instead the sample should be suitable for drawing meaningful conclusions relevant to the mechanisms or outcomes of interest. The studies in this review have sourced participants from appropriate sources and organisations of young people with autism.

1.2 Training for ESM Data Collection

All 10 studies (100%) reported that researchers provided training for participants utilising ESM. All studies explained the ESM procedures and how young people were trained to use the survey designs or technology. However, there was significant variation in the level of detail provided so gaining a full sense of the extent of the training received is challenging. For the three studies (N=30%) that did not complete practice trials of completing an ESM assessment, one study (N=1, 10%) reported that their training procedure lasted 60 minutes and assisted in installing the ESM app, one study (N=1, 10%) provided training in how to complete ESM and asked the young person questions to clarify their understanding using a 'teach back' method. Finally, one study (N=10%) provided an overview of their ESM procedure and provided screenshots of the what the ESM prompts would look like. Seven

studies (70%) incorporated practice administrations and trials into their training procedure. Practice trials ranged from participants trialling this once within the initial overview session to a 3-day trial of ESM independently.

Most studies included both the young person and their caregiver (N=8, 80%) during the training procedure. The remaining two studies (20%) completed ESM training with just the young person present. There were no further comments regarding making adaptations to training specifically for children and young people with autism. The intensity of training provided to participants did not appear to positively influence the compliance rate. Two studies who provided a 3-day trial prior to completing the ESM procedure had a lower compliance rate reported at 56.8% (ranging from 41-76%). It may be hypothesised that trialling the ESM schedule over a period of days prior to study completion could increase participant burden, minimising the motivation and willingness once the study duration begins.

1.3 Compliance Rate and Attrition

The ESM compliance rate is one of the key indicators of feasibility and can be defined as the ratio of the number of completed ESM beeps that participants completed over the theoretical maximum number of beeps allowed by the protocol (Vachon et al., 2019). These are generally presented as a percentage (0-100% compliance). Ascertaining the compliance rate during ESM studies helps to gain a sense of the feasibility for the sample population to complete the measures presented. One paper (Dallman, 2020) did not break down compliance rate overall but broke this down into participants who completed over 60% of responses (N=12) and under 60% of responses (N=5). The remaining nine studies reported the mean compliance rates for participants with autism which ranged from 56.8% to 85%. The mean compliance rate for the nine studies was 71%. All 4 (40%) studies that included a control group of neurotypical participants reported the mean compliance rate for the control groups which ranged from 78% to 93% and had an overall mean compliance across the four studies of 86.4%. Compliance rates fell within rates described by other reviews and meta-analyses of ESM with children and young people (54.6% to 96.21%, Wen, Schneider, Stone et al., 2017) and ESM studies with individuals with autism (range 63-92%, M= 71%; Chen, Bundy, Cordier et al., 2014).

Providing participants with an incentive for participating has been associated with higher compliance rates compared with no incentives which in turn increases data quality and willingness to participate (Wrzus and Neubaur, 2023). Of the 10 included studies, 80% (N=8) did not report providing participants with incentives such as monetary compensation or providing individuals with personalised graphs of their results. One study (10%) provided participants with a \$20 telephone credit voucher as a partial re-imbursement for their time in the study. One further study (10%) did provide a participant contingent compensation incentive whereby the compensation received was dependent on the number of ESM beeps they completed during the study period but did not provide further details on this. No studies reported provided personalised graphs of their ESM data as an incentive.

The retention rate for ESM is recognised as the proportion of participants that were included in the final analyses (e.g., withdrawing from participation; Vachon et al., 2019). Researchers will often choose to exclude participants who have a sub-optimal compliance rate thus influencing the retention rate. However, there is no definite rule regarding the specific threshold percentage and so it varies throughout the literature. However, the more missing data included in final analyses, the harder it would be to assume data is missing randomly making data less likely to be reliable (Trull and Ebner-Priemer, 2020).

Two studies included in the review set a compliance threshold of 60% and for participants who did not reach this, they would then be excluded from analysis. Two studies reported that three participants withdrew prior to any data collection and measures being completed, no further reasons were provided. One study deemed a participant's data unusable as the ESM beeps had been completed by a caregiver and not the young person. Also in one study, a participant with autism did not provide a response for the last 14 ESM calls, and so was excluded from the analysis and a control participant was deemed a non-completer due to the compliance rate being under the 60% compliance threshold. A further study reported excluded a participant after data collection as they were reported to have an intellectual disability thus no longer meeting criteria.

1.4 Overall Review of Feasibility of ESM with Children and Young People with Autism

All 10 (100%) studies regarded ESM as a feasible methodology to gather data within the everyday life context of young people with autism. All studies were able to recruit participants, train them to follow the ESM procedure with a satisfactory to good level of compliance to provide meaningful data and analyses. Of the included studies, participant attrition was not evident to impact study analysis and overall feasibility. A small proportion of studies excluded participants from analysis if they did not meet pre-agreed compliance thresholds. Many studies had small sample sizes and/or included only males so findings were not always able to be generalised out to the wider population. Moreover, the use of reading level assessments and IQ thresholds meant that participants included in the studies were more likely to find the ESM procedure feasible to complete. Studies lowered the complexity of language used within the ESM items, and for some studies pictorials and visuals were used to assist in ESM item completion. Individuals with more significant cognitive difficulties were not included in the studies for this review, so the broad range of needs and strengths between individuals with autism was not fully understood by this present review. No studies reported difficulties or distress associated with light or noise sensitivities triggered by ESM prompts.

Further Factors to Consider with ESM Studies

Topic 2: Sample Characteristics

2.1 Sample Characteristics

Study sample sizes varied from 6 to 133 participants with a mean of 35.8 participants. Nine out of ten studies had a sample size under 40, with a mean of 25 participants across those nine studies. Participants age ranged from 8 to 19 years old, with a mean age across all studies of 13.4 years old. Of the 10 studies, 6 included a mix of genders and 4 included males only. Two studies (Dallman et al., 2020; 2022) reported that they excluded females from their sample due to low sample sizes and the exploratory nature of the research. Studies included in this review were conducted in Australia (N=4), the United States of America (North Carolina (N=4) and Pennsylvania (N= 1)) and Taiwan (N=1).

This review explored the use of ESM with children and young people with autism, thus the included studies required their sample of participants to have a diagnosis of autism spectrum disorder or Aspergers Syndrome. Researchers confirmed this in a variety of ways. Four studies (N=4, 40%) confirmed that participants had a formal diagnosis of Autism spectrum disorder (ASD), high-functioning autism (HFA) and in some articles also Aspergers by ensuring participants had received a formal diagnosis from a psychiatrist or paediatrician. Two of these studies (N=2, 20%) reported specifically that this should be in line with the DSM-IV-TR or DSM-V criteria.

Four studies (N=4, 40%) confirmed participants met this inclusion criteria by utilising the Autism Diagnostic Observation Schedules (ADOS). For two of these cases, parents also provided additional information of which one (N=1) completed the parent Autism Diagnostic Interview- Revised (ADI-R) and one (N=1) reported gaining a “parent report”. In one (N=1) of these cases, confirmation of participants scoring above threshold was confirmed by the research registry. Two studies (N=2, 20%) ensured participants met DSM-V criteria for ASD or Aspergers by conducting case reviews of diagnostic reports. One of these studies, in addition, completed the Social Communications Questionnaire.

Less than half – 4 out of 10 (40%) - of the studies included a control group of neurotypical children and young people. When a control group was included research studies aimed to have groups with similar mean ages and characteristics (i.e., ethnicity/race). Kovac et al. (2015; 2016) and Rump (2011) reported that their control group consisted of typically developing peers with a similar mean age and mean IQ. Chen et al. (2023) reported the control group to have a mean of a similar age and ethnicity to the ASD group.

Topic 3: ESM Data Collection Methods

3.1 Sampling Duration

The sampling duration ranged from 4 to 14 days across the studies, The most common assessment durations were 7 days (N=5, 50%) followed by 14 days (N= 3, 30%), and 4 days (N=2, 20%) respectively. All studies included ESM observations over both weekday and weekends. When sampling durations were over 4 days, studies implemented ESM

observations on Friday, Saturday, Sunday, and Monday (Kovac, 2015; Kovac et al., 2016). All studies completed ESM data collection over one duration wave. No studies completed a 'measurement burst' whereby participants would complete a period of ESM, have a break period, then continue with more ESM data collection.

3.2 Sampling Frequency

All studies (N=10) signalled participants to complete ESM assessments throughout the course of the day at either random (unknown times) or fixed times (that participants were aware of in advance). Across all studies, participants were prompted to complete ESM assessments between two and seven times per day ($M = 5.65$ times/day). Of the studies that completed 4 days of ESM assessments, both studies completed 6 beeps per day. Studies that had a 7-day ESM duration, sampling frequency was set as either 6 beeps per day (N=2) or 7 beeps per day (N=3). Three studies had a sampling duration of 14 days, two of these studies had a sampling frequency of 4 beeps per day. One study had a different sampling frequency for the day of the week with weekdays having 2 beeps per day and weekends with 5 beeps per day. This indicates that within these articles, when a longer sampling duration is used typically the sampling frequency is less.

3.3 ESM Prompt and Sampling Design

Three studies (30%) reported utilising a random sampling ESM prompt design. For these studies, participants ESM beeps would be received at completely random times within participant waking hours and participants would not be able to guess when their next beep would be given. Five studies (50%) ESM beeps were prompted using a semi-random sampling design. Three of these studies (30%) reported that prompt was provided randomly within pre-determined time intervals. Two of these studies (20%) had a random first ESM notification, then subsequent notifications were not randomised (i.e., every 2 hours after the first beep). One study (10%) reported that they utilised 'automated' beeps but did not specify the sampling type of these automations. Also, one study (10%) reported utilising 'pseudo- random sampling'.

Three studies (30%) reported setting time parameters on the ESM beep so that after a set time it would time out and not record responses. Two studies (20%) set the parameter of 2 minutes to enter their answers, whereas one study reported that participants had to open the ESM notification within 3 minutes of the initial prompt and complete the item fully within a 5-minute period. Where a time limit was set on participant responses, the mean time to complete entries ranged from 59 seconds (SD=42s) - 1 minute and 53 seconds (no SD reported). One study did not set a time limit but did report a mean completion time of 59 seconds (SD= 42s).

3.4 Hardware/Software

All studies required participants to have access to a mobile phone or iPod touch to complete ESM observations. Half (N=5) of the included studies used applications to administer and log ESM data – four of which utilised this via a smartphone and one via an iPod Touch. The studies used two different types of smartphone applications including the 'Participation in Everyday Life Application' (PIEL App; Jessup et al., 2012) and the 'mobiletype' program (Reid et al., 2009). Application development is often time and money-consuming so it is expected that researchers will opt for developed applications that can be modified per research query. It is crucial for researchers to collaborate well and produce well-tested applications to ensure good app usability and reduce technical factors which contribute to participant attrition (de Vries et al., 2021).

Of the 10 studies, 40% (N=4) utilised text prompts to participants containing a website link that redirected participants to complete an electronic questionnaire as part of the ESM data collection. For one of these studies, they identified that some young people were unable to have access to texting capacities, so in this instance they received ESM observations via telephone calls. One study (10%) had designed the ESM study for young people to receive ESM prompts via telephone calls. Three studies (N=3, 30%) provided participants with the use of a mobile phone, and two studies (N=2, 20%) provided the use of an iPod touch for the purpose of the study. The remaining five studies (N=5, 50%) did not provide participants with access to equipment to complete ESM data collection. Although two studies (Kovac, 2015; Kovac et al., 2016) did not provide participants with a mobile phone, if

their phone was unable to receive texting prompts, they amended their procedure by organising ESM data collection via phone calls. Two studies (Dallman et al., 2020; 2022) excluded one participant for not having their own mobile phone to use for the study.

The use of technology for ESM research has helped to address non-compliant behaviour, such as ESM items being backfilled or completed in bulk, present in earlier ESM research that yielded biased data. This is addressed with digital devices as prompts can be set up to 'time-out' after the allotted time and data entries are also automatically time-stamped contributing to more reliable measurement of participant compliance compared with non-digital methods (Wen et al., 2017). The studies included in the review highlighted the feasibility of using digital means to gather time-variant data with children and young people with autism.

Discussion

The aim of the present review was to synthesise the evidence on whether ESM is a feasible methodology to use with children and young people with Autism. Previous research reported concerns that the ESM design could be inaccessible for the wide-ranging variation of needs and preferences related to ASD diagnoses. Concerns around an individual's ability to manage shifts from daily routine or tasks of interest (with or without additional support), the inconsistent and unpredictable prompting of ESM and lastly, difficulties in emotional self-awareness including identifying and describing one's own feeling in the moment were raised (Chen et al., 2014).

There is a lack of research on the use of self-report measures for children and young people with Autism. Research with adults with ASD has suggested that individuals with ASD tend to under-report difficulties due to limited social insight and so their responses may provide a more conservative estimate of their level of impairment and impact on their daily life (Sandercock et al., 2020). This potential inaccurate or under-reporting can negatively impact intervention planning and implementation. Moreover, static measurement tools may not offer the sensitivity required to measure variables of interest in an individual's naturalistic environment, thus are unable to provide rich within-person contextual data and

facilitate a greater understanding of the daily experiences (Fazeli et al., 2019). ESM is a methodology that aims to manage these methodological limitations.

Utilising ESM is suggested as an ecologically valid methodology that can account for the limitations observed with static self-report measures. The present review suggests that ESM has been shown to be a feasible methodology for use with the adolescent samples included in this review. Although the studies included in this review required participants commitment to respond to ESM prompts across the day and study duration, ESM attrition and compliance rates were not negatively impacted. Participants included in this review were able to feasibly utilise the ESM format to provide data across the study period with each study thus not negatively impeding protocol validity. All studies were able to utilise data within the study to produce findings that informed future research, although when sample sizes were small the generalisability was cautioned. As such, ESM via digital and phone means constituted a feasible research methodology for many topic areas with children and young people with autism if relevant designs, adaptations, and modifications for the target population are considered. When considerations regarding ESM planning (e.g., training provided, support from caregiver/guardian, use of incentives), design (e.g., number of prompts a day, scheduling of prompts and study duration), and implementation for the intended population (i.e., age and understanding of needs of the participant group) are tailored, high quality and valid data can be obtained. Although not directly explored within this review, it is suggested that the use of ESM can help address issues relating to retrospective recall. Moreover, the flexibility of utilising digital devices to gather data through prompts helps to broadly navigate difficulties with data collection with children and young people.

One key barrier for the feasibility of ESM is the requirement for participants to own or be able to access research equipment to take part in the studies. Five (50%) studies did not provide participants with a study phone or iPod to complete ESM beeps. These studies relied on participants having access to their own equipment, as well as having phone data or wireless internet to connect the devices to allow ESM prompts to occur. This could lead to additional barriers for children and young people with autism from lower socioeconomic backgrounds being able to participate in research studies. Moreover, participants of the

younger age groups may not have been allowed by their caregivers to have their own personal smartphone due to their age which may reduce who would be able to participate if a study phone was not provided. Researchers should therefore consider the accessibility of technology and the internet data required to run the applications whilst designing ESM studies and where possible provide these for study participants.

The average compliance rate, a key indicator of feasibility, ranged from 56.8% to 85% which is in line with a previous meta-analysis across samples where compliance ranged significantly, but most – around 97.4% - reported compliance greater than 50% (average 79.19, SD=13.64%; range 9.83-101.85; Wruz and Neubauer, 2023). Greater compliance, within this review, occurred for studies that utilised less frequent ESM prompts daily over a shorter study duration (i.e., 6 beeps daily over 4 days compared to 7 beeps daily for 7 days). Moreover, involvement of parent and caregivers, as well as teaching staff was noted to help increase compliance rates. More intensive training (i.e., 3-day trial period of ESM schedule) provided to participants did not appear to positively influence compliance rates, and in turn these studies produced lower compliance rates compared to the other studies. When piloting ESM research designs, researchers should aim for a visual question format (i.e., slider scales, less response options, and pictorial/visual displays), with the right balance and combination of the frequency of assessments per day, and the study duration for the target population (Chen et al., 2015). Tailoring the design correctly can assist in attaining optimal compliance rates contributing to findings having greater validity and be generalised more reliably with the population out with of the study. Creating ESM item schedules through co-design, consultations and testing with children and young people with autism could offer valuable insights into amendments that could be made to improve compliance rates prior to the study commencing (Chen et al., 2016).

Future studies should aim to adhere more closely to CREMAS guidance to enhance transparency, reproduction of research, and allow reviews to gain a greater understanding of ESM study characteristics and sample effects. Moreover, the development of a validated quality assessment tool for ESM studies would be a beneficial addition to ensuring high quality of research papers.

Limitations of Studies

There are several key limitations within the participant sampling of the present review to consider with regards to understanding feasibility. Firstly, the included studies utilised convenience sampling approaches where studies recruited participants through leaflets, social media and through relevant registries. They did not utilise any form of random selection. Although convenience sampling is one of the most common sampling strategies in research due to its ease, time-efficiency and low costs it has a significant disadvantage of limiting the generalisability (Jager et al., 2017). The findings cannot be easily generalised to populations with characteristics that differ from the population that was conveniently accessible and whereby the sample was drawn (Andrade, 2021). Moreover, convenience sampling can create the risk of sampling bias as the sample was drawn from convenience and not equal probability so the samples in these studies do not result in a statistically balanced selection of the population.

Secondly, the studies included in the review focused on children with high functioning autism and did not consider the feasibility of ESM for those with more significant cognitive functioning difficulties and intellectual disabilities. The feasibility for the broad range of needs in ASD is therefore not clear as these studies, which were not included in this review, typically use caregivers to complete ESM on behalf of young people with autism (Bangerter et al., 2019). It would be important to explore the feasibility of ESM with a broader range of ASD needs to determine the true capabilities of the methodology and design when tailored appropriately. For example, it would be interesting to know if this methodology could be utilised with those with greater cognitive difficulties with the appropriate adaptations; such as significant training with the participant on a 1:1 basis, building the use of the model up via gradual exposure with the participant, and the use of visuals that are meaningful to the participant's current daily routine made in collaboration with speech and language professionals.

Furthermore, many studies also recruited a small sample of participant, and so caution should be applied when interpreting findings of this research, especially if the sample is uncontrolled. Furthermore, two studies reported excluding females due to a significantly small sample size of females, thus overall, there is an inadequate representation of females

in their samples despite high prevalence of mental health difficulties for females with autism (Ross et al., 2020). This may also reflect the inadequate representation within the autism diagnosis process whereby females are at a disproportionate risk of not receiving a clinical diagnosis due to the differences in how autism presents in females and so are less likely to be referred for autism assessment (Loomes et al, 2017). As such, the studies within this review were unable to address whether ESM is a feasible methodology for use across genders as the majority did not include or discuss issues relating to gender differences within their research.

As well as a small sample size, biased sampling methodology, and unrepresentative gender sampling, the research studies were also only conducted in three geographical areas: Australia, Taiwan and the USA. As such, gaining a broad understanding of the feasibility of ESM within a range of countries, cultures and contextual environments has not been conducted. Interestingly, a high proportion of studies excluded from the review included the methodology and characteristics required as per the inclusion criteria but the upper age range limit of the studies was 30 or 45 years old (e.g., Chen et al., 2016; Feller et al, 2023; Ilen et al., 2023). These studies kept the participant sample as a whole group and did not break down the participants sample into child, adolescent, or emerging adult categories. As such, these studies could not be included in the review as it would not be possible derive meaning in relation to the review aim due to the overgeneralisation of the participant sample. The rationale for the age-range for these articles was not provided and unfortunately due to the sample not being broken down into age ranges, crucial information on the feasibility for some participants who would have met the criteria was unable to be observed. As such, the findings of these studies are not widely generalisable.

A further limitation of the review is that the included studies varied in adherence to the CREMAS guidelines, and as such their quality, transparency, and reproducibility. However, this can be understood to some extent as seven of the ten studies were published prior to the guidelines being developed. The ESM field could benefit from the production of a quality assessment tool to improve methodological and design rigour. Moreover, an approved and validated assessment tool would ensure that included review articles are assessed for ESM specific design features, as well as more general research design features.

Conclusion

This review has highlighted that experience sampling methodology can be a feasible methodology to explore key mechanisms for children and young people with autism, specifically high functioning autism, when adapted appropriately (i.e., item schedule adapted to suit comprehension and design the right balance of frequency and duration). However, included studies failed to address the broad range of cognitive abilities with individuals with autism when using ESM and the required modifications that may be required for this population. Future studies should provide a sample that encompasses children and young people with autism more broadly to understand the feasibility of utilising ESM for young people with a range of cognitive abilities. Moreover, a sample that includes a greater representation of males and females with autism, and where possible includes a control group, could assist in recognising if there are any gender differences in utilising ESM for young people with Autism. Future studies should aim to report their ESM study in adherence to the CREMAS guidance and specific handbooks for ESM (i.e., The Open Handbook of Experience Sampling Methodology; Myin-Germeys and Kuppens, 2022).

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Chapter 2: Empirical Project



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**Exploring mentalization, the impact of trauma, and the mediation of
perceived social support on wellbeing in the daily life context of help-seeking
young people attending CAMHS: An Ecological Momentary Study**

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Word Count (excluding references): 10324 words.

Author notes: No known conflicts of interest to disclose.

Written for submission to the British Journal of Clinical Psychology. See Appendix 11 for Author Guidelines.

Abstract

Objective: Individuals who experience adverse childhood events or trauma have an increased risk of experiencing poor mental health. The theoretical background of mentalization suggest that mentalizing is a dynamic and context dependent transdiagnostic factor related to mental wellbeing. Perceived social support has also been described to vary within different contexts and play an indirect role in one's mental wellbeing. As such, the present study aimed to explore the relationships of mentalization, the impact of trauma, and the mediational influence of perceived peer support on children and young people's mental wellbeing.

Method: Twenty-seven participants attending specialist and general mental health services in Edinburgh were recruited. Demographics, trauma event occurrence and the perceived impact was gathered using a trauma checklist via a survey platform. Experience sampling, via the smartphone application m-Path, was used to assess mental wellbeing, event-specific mentalization and perceived social support six times a day over a 7-day duration period.

Results: Multilevel models indicated that momentary mentalization was significantly negatively associated with momentary mental wellbeing. Momentary perceived social support was also significantly associated with momentary mental wellbeing. There was no significant interaction effect observed between momentary perceived social support and the average trauma impact. Lastly, structural equation models indicated that both mentalization, perceived social support and the impact of trauma had a significant association with momentary mental wellbeing.

Conclusions: This study was one of the first to explore the dynamic nature of mentalization, perceived social support and mental wellbeing in a sample of children and young people with trauma experience in the context of their everyday life. Preliminary evidence that mentalization and perceived social support are important factors in the day-to-day fluctuations of mental wellbeing are highlighted. Perceived social support was found to mediate the relation between mentalization and momentary mental wellbeing. Moreover, future research on the time-variant nature of these factors and their relationship with one another would be important to inform research and clinical practice.

Keywords: *ecological momentary assessment, adolescence, trauma, mentalization, perceived social support, mental wellbeing*

Practitioner Points:

- Event specific mentalization, perceived social support and mental wellbeing are all concepts that should be operationalised and measured in a dynamic and time-variant way to gain an understanding of the fluctuations that occur between and within individuals. No study has explored these concepts together using a time-variant approach.
- Experience sampling methods were used through six semi-random sampling prompts over a 1-week study duration through participants' digital devices.
- The mentalizing of others showed a significant negative association with momentary mental wellbeing, momentary perceived social support had a significant positive association with mental wellbeing. There was a significant moderating relationship of momentary perceived social support and average trauma impact.
- The findings have implications for further research suggesting that mentalizing can be measured using ESM with children and young people from a clinical sample.

Introduction

Adolescent Mental Health

Adolescence is a developmental stage characterised by significant change: biologically, psychologically, and socially including increased psychosocial opportunities and potential risks (Blakemore, 2019; Clarke et al., 2020). As such, adolescence confers considerable vulnerability for the onset of poor mental wellbeing. The World Health Organization (WHO) defines mental wellbeing as a state of wellbeing in which every individual realises their own potential, can cope with the stressors of their life, can work productively, and contribute to their community (WHO, 2014). Approximately 10% of children and young people in Scotland have a diagnosable mental health diagnosis, with 50% of mental health difficulties established by the time the young person reaches seven years old (Mowat, 2019). Evidence also indicates that the rate for mental health difficulties is higher for adolescents from more deprived and minoritised backgrounds (Deighton et al., 2019; Bhugra et al., 2020). The increasing prevalence of mental health difficulties among adolescents is expected to be further exacerbated by the COVID-19 pandemic (The Lancet, 2021; Wolf et al., 2024). Wolf and Schmitz's (2024) review explored the longitudinal effects of the COVID-19 pandemic on child and adolescent mental health. The results from 69 studies indicated a general trend of less psychological well-being and more mental health difficulties including heightened stress, anxiety and depression symptomology. Both protection measure intensity (i.e., lockdowns, general restrictions) and infection dynamics were positively associated with mental health difficulties (Wolf et al., 2024). As such, children and young people's mental wellbeing has become a growing priority in public health policy with the growing recognition and interest in minimising the risks associated with the onset and maintenance of mental health difficulties (The Scottish Government, 2017; Toma, Anderson, Forster et al., 2022).

Experiencing traumatic events during childhood is also associated with elevated risks and vulnerabilities that affect behaviour, functioning and mental wellbeing across the lifespan (Copeland et al., 2018). Traumatic events can be defined as single incidents (e.g., accidents, natural disasters, medical trauma), or multiple or repeated events (e.g., interpersonal violence, neglect, emotional, physical, and sexual abuse). Around 33%-50% of young people living in the United Kingdom will have experienced at least one traumatic event or adverse

childhood experience (UK Trauma Council, 2020; Torjesen, 2019). Torjesen (2019) reported that the experience of childhood trauma doubles a young person's risk of experiencing a mental health difficulty. Trauma experiences during childhood and adolescence is predictive of a poorer course of mental health difficulties, earlier age of onset, poorer social outcomes, and higher rates of suicide (Devi et al., 2019).

Trauma should be understood in the context of the individual's experience of the event (Sweeney, et al., 2018). Research has shown that the absence and presence of accumulated trauma events, and/or the type of trauma event experienced, is less relevant on one's mental wellbeing than the complex interplay of subjective characteristics of these experiences for individuals, such as the perceived impact and meaning, and perception of available or lost resources (i.e., social support; Charuvastra and Cloitre, 2008; Muldoon et al., 2019). The experience of trauma is complex as a variation of factors influence the impact on the individual including the type of trauma experience, the source (i.e., family, peer, professional, unknown person etc), the chronicity and the developmental stage at which it occurred or began (Blaustein and Kinniburgh, 2010). Furthermore, the individual's context – such as their family, community, school experience, culture, and beliefs- can facilitate either buffering or exacerbating effects on the impact of trauma on the young person. The buffering effects from key protective mechanisms (i.e., social support, attachment, mentalization) can help to foster adaptive resilience contributing to more positive mental health outcomes for children and young people who have experienced traumatic events (Dowdy-Hazlett, et al., 2021). As such, how a traumatic event is perceived and processed by the individual, as well as other psychological mechanisms, influences the potential negative impact on everyday functioning, life satisfaction, mental and physical wellbeing, and developmental outcomes (Schlack, et al., 2021).

Mentalization

Mentalization is a trans-diagnostic and multi-dimensional process relevant for a multitude of mental health difficulties (Ballespi et al., 2018; Horz-Sagstetter et al., 2015).

Mentalization is an imaginative capacity to interpret and understand – both implicit and explicit – behaviour of self and others as an expression of intentional states (thoughts, feelings, beliefs, and desires (Fonagy et al., 2002). It develops within the context of early

caregiver relationships where caregivers can recognise, understand, and hold in mind that their child has their own mind, feelings intentions and desires (Fonagy and Target, 1997). When a caregiver lacks the capacity to reflect on and understand their own and their child's mental states, it can be more challenging for the child to develop a sense of self contributing to interpersonal difficulties (e.g., difficulties with boundaries and understanding others (Bammens et al., 2015; Bateman and Fonagy, 2016; Fonagy et al., 1998;)). Mentalization plays an important role in affect regulation, self-control, self-monitoring and can provide the reflective mental buffer sustaining the inhibition of impulsive behaviours in emotionally laden or distressing contexts (Fonagy et al., 2007; 2018; Sloover et al., 2022).

Adolescence represents a critical developmental period for the maturation of mentalizing capacity, as through acquisition of new cognitive capacities, a more complex understanding of mental states, emotions and behaviours are considered (Frith and Frith, 2006; Desatnik et al., 2023). Experiencing trauma during the formative periods of child development can impede the development of mentalization and cause changes in mechanisms of arousal contributing to a relatively ready activation of the attachment system leading to offline mentalizing in response to relatively mild emotional stimuli (Arnsten, 1998; Garon-Bussonette et al., 2023; Weinstein et al., 2016). When adolescents struggle to take a mentalizing stance, they are more vulnerable in stressful situations and may inaccurately interpret the information and the behaviour of others by becoming inflexible, biased, and non-reflective in the ideations about the self and others (Locati et al., 2022). Optimal and robust mentalizing is when the right kind of mentalizing is used in the right context. Robust mentalization allows individuals to mentalize under stress and to recover relatively quickly from lapses of mentalization (Bateman and Fonagy, 2013). Mentalizing fosters self-regulation and bonding, which in turn helps equip a developing child to cope with the stressors that are inevitable in life as well as further unexpected adverse experiences (Sharp and Bevington, 2022).

Theoretically, it is suggested that individuals will fluctuate in their capacity to mentalize depending on the context, including one's arousal level, attachment context and mental states of self and others (Fonagy et al., 2012). However, a vast array of research has explored mentalization through a static operationalisation that shows individual differences

but does not focus on within-person differences across time or contexts (Steinberg, Moshe-Cohen, Sheena et al., 2024). Also, many studies do not measure mentalization at a time when participants report being distressed when they would likely be experiencing an activation of the attachment system (e.g., Wagner-Skacel et al., 2022). As such, these studies neglect to capture the dynamic nature of mentalization and the contextual information related to a participant's mentalizing. Considering this, as mentalization is understood to be contextually variant, the current study aims to investigate fluctuations in mentalization in context and in accordance with the theoretical background of attachment activation following a perceived stressful situation.

Perceived Social Support

The role of social support is significant in the prevention and maintenance of mental health difficulties (Wang et al, 2018; Ivar Bjorlykhaug et al., 2022). Social support can be difficult to operationalise globally, and its meaning may be dependent on the context of this support (i.e., for new parents, adolescents, older adults; Williams et al., 2004). For this study, social support will be operationalised in the context of adolescents and refers to the extent to which an individual perceives they have access to assistance and resources provided by people in their social network (Bauer et al., 2021). Perceived social support can be defined as an individual's belief about the potential availability and quality of social support from others available to them (Ruiz et al., 2013). Petersen et al. (2023) stated that perceived social support has been consistently associated with high wellbeing and low levels of emotional symptoms, more so than other measures of support including social networks (i.e., the number and type of social relations).

Social support, in the adolescent context, can be multi-faceted and can often be provided by different people in their lives. Adolescence is a developmental period where social tasks include gaining more independence from caregivers, navigating complex peer social hierarchies, nurturing intimacy in friendships and exploring romantic relationships (Williamson and Mills, 2022). However, due to social rejection, exclusion and individual differences this relational development does not occur similarly for each adolescent (Lynn-Mulvey et al., 2017). Thus, perceived social support will likely also be experienced differently for everyone. Moreover, adolescents may perceive social support differently depending on

the context in which they are in (i.e., home, school, after school socialising etc). Research suggests that social support improves mental health outcomes indirectly as a buffer against negative effects of distressing stimuli and situations which weaken the association with mental distress (Uchino et al., 2018; Petersen et al., 2023). Young people who have experienced trauma have shown to have better mental health outcomes and increased resilience when they are well supported by parents, caregivers, friends, and other close relationships (Acoba, 2024).

Many studies measure social support by assessing the structure of or functions of one's social network (Gottlieb and Bergen, 2010). However, the decision to measure perceived social support for this study stemmed from research suggesting that the beneficial effects of social support may be explained to a greater extent by positive perceived, and often fluctuating, feelings associated with the support, rather than the actual received social support (Acoba, 2024; Maisel and Gable, 2009). ESM studies on momentary perceived social support have shown considerable variation in perceived social support over hours and days, thus supporting the rationale to explore the within person variation of perceived social support in naturalistic settings (Coppersmith et al., 2019).

Experience Sampling Methodology (ESM)

The dynamic nature of mental wellbeing, mentalization and perceived peer support for children and young people needs to be measured in a way that accounts for these variations within an individual, as well as for between person differences. Experience sampling methodology, also known as ecological momentary assessment, refers to sampling methods that consist of structured self-reports using a diary technique investigating affect, contextual factors, and an individual's real-time appraisals (Myin-Germeys & Kuppens, 2022).

Investigating self-reported symptomology or factors within the daily experiences of one's natural context is not novel as previous studies utilised diary methods, booklets or the manual input from researchers following phone calls with participants (Deakin et al., 2022; de Vries et al, 2021). However, ESM by digital means (i.e., mobile phone, tablets) is increasing in popularity due to technological advancements increasing accessibility and convenience for both researchers and participants (van Dalen et al., 2023). Further practical advantages of utilising digital ESM include participants' responses automatically being coded

with a timestamp and if using an ESM app program, data can also be automatically backed up reducing the likelihood of data being lost. Researchers can also set additional prompts and time parameters for responses which could increase the probability of assessments being completed increasing the validity of the data (Chen et al., 2015).

ESM is a dynamic and time variant measurement that is typically repeated several times in a day over a planned study duration (i.e., 7 days). It is 'ecological' by design as it samples variables in a participants' natural environment and it is 'momentary' as participants are asked to complete multiple random brief repeated assessments regarding events and experiences in real-time (Russell and Gajos, 2020). This offers the opportunity for researchers to explore variables of interest, and their variability through time, both between and within participants to a greater level than static measures. Moreover, due to participants completing assessments in the moment several times throughout the day, there is a reduction in recall bias compared to other static and retrospective self-report measures (Myin-Germeys & Kuppens, 2022). The negative memory bias, often called the 'memory experience gap', suggests that a participant will report experiences as more intense or negative when recalling from memory than they do when reported at the time (Ellison et al., 2020).

Overview of the Present Study

As mentioned above, many research studies utilise static questionnaire formats to investigate mentalization despite the theoretical background suggesting that mentalization is dynamic in nature and depends on the context and activation of the attachment system. Therefore, this study aimed to address the gaps by utilising experience sampling methodology via digital means as an assessment method that captures data in the context of adolescents' daily life in a clinical population. To the best of our knowledge, only one pilot study (Steinberg et al., 2024) has explored mentalization in this way with a non-clinical adult population of undergraduate students. The present study is the first study to date to explore mentalization by mean of a novel and momentary assessment method with a clinical population of adolescents. This proof-of-concept research will also investigate the mediating role of perceived social support, which will also be measured in the context of participant's daily life. The study will aim to explore both momentary mentalization and momentary

perceived social support in relation to the momentary mental wellbeing of children and young people attending CAMHS and their self-reported impact of trauma. Some children and young people who experience traumatic events may clearly present with symptoms associated with criteria for posttraumatic stress disorder (PTSD) according to diagnostic manuals. However, some young people may score sub-threshold of the PTSD criteria but still report symptoms that have a significant and detrimental impact on their daily life and functioning (Klein et al., 2024). Considering this, the present study will explore self-reported trauma event experiences, and the self-reported impact of these events rather than utilise diagnostic screeners.

Research Questions

2.1.1 Primary Research Questions

- Does momentary mentalization predict momentary mental wellbeing for trauma experienced children and young people?

A higher momentary mentalization capacity will positively predict momentary mental wellbeing.

- Does momentary perceived social support predict momentary wellbeing for trauma experienced children and young people

Momentary perceived social support will positively predict momentary daily wellbeing.

- Is there an interaction between momentary mentalization and momentary perceived social support for trauma experienced children and young people?
- In the context of their daily lives, how might momentary perceived social support mediate the relationship between momentary mentalization and momentary mental wellbeing for children and young people attending CAMHS?

Methods

Design

The intensive longitudinal design of experience sampling methodology (ESM) was utilised over a 7-day study duration. This is line with previous ESM research, as shown by a meta-analysis highlighting that that from 79 datasets, 68% of studies lasted between 2-10 days (Vachon et al., 2019). These seven days were consecutive for most participants and within 2-hour blocks unless the participant highlighted difficulties completing allocated slots (e.g., school not allowing phone use and so participants were unable to respond to phone prompts). The interview schedule consisted of six core ESM questionnaires. Assessments used a semi-random sampling scheme, whereby prompts were randomly generated within multiple pre-defined time intervals. The assessment prompts could occur between 9am to 10pm for most participants, although these varied according to participant preference to minimise participant burden (i.e., amending ESM observations in line with participants' usual wake/sleep routine & dependent on ability to complete in school). This is consistent with signal scheduling methods utilised in previous momentary sampling research with children (Khor et al., 2014). This design was chosen to be as minimally disruptive to children and young people as possible. Participants did not all complete the ESM data on the same day as each other as recruitment and testing occurred over a period of three months. The seven-day ESM testing period allowed for the inclusion of weekday and weekend data which helps to encapsulate a variation in context and potentially a different impact on key variables.

Ethical Approval

Ethical approval was granted from The University of Edinburgh School of Health in Social Science (Appendix 1) and NHS Research Ethics Committee (Appendix 2).

Materials

Information sheets (12–15-year-old version, 16–18-year-old version and parent/guardian version; Appendix 4, 5 and 6 respectively) were provided as hard copies and emailed to participants interested in taking part in the study. The consent form was completed in person during face-to-face enrolments or over the phone during phone call enrolments. All consent information was stored via 'Qualtrics', an online survey software. Demographic and

baseline questionnaires were completed via Qualtrics by all participants. ESM data was collected on an application platform called 'M-Path Sense©' (<https://m-path.io/landing/>; Mestdagh et al., 2022) which was developed by KU Leuven and compatible with both iOS and Android smartphones. ESM item schedules were trialled by study researchers to ensure items were appropriate for use with young people, could be completed promptly (within 1-2 minutes) and had no technical errors. It is recommended that ESM questionnaires take preferably less than 3 minutes to complete (Myin-Germeys and Kuppens (2022)). If young people did not have access to a phone appropriate for using the application's software or did not have suitable phone credit, study phones and credit vouchers were available. No participants requested use of a study phone or credit. Participants received a gift card as compensation for their time provided virtually or in person in the debrief appointment following completion of the study.

Participants

Participants were recruited through convenience sampling from general and specialist NHS child and adolescent mental health services in Scotland. Participants were eligible for enrolment to the study if they were: aged 12-18 years old, receiving active care from a CAMHS service in NHS Scotland and were understanding of the study. The exclusion criteria included participants with a formal diagnosis of an intellectual disability and current intent to act on suicidal ideation. The criteria were presented to all CAMHS teams during their weekly team meeting, and they were asked to share the study information with young people in their service. If a young person consented to a researcher contacting them, the clinician would pass the young person's name and telephone number to the researcher. Additionally, leaflets and posters with a Qualtrics QR code were advertised in CAMHS waiting rooms to allow participants the opportunity to self-refer to the study. To self-refer, a young person provided their name, age category, the CAMHS service they received care from, phone number and email address. If a young person, identified by a clinician or via self-referral, was interested in taking part in the study they would receive a text or telephone call providing further information on the study. Information sheets were emailed to all young people, and if 13-15 years old, the participants' parent/guardian would also receive an information sheet and informed that they were able to opt-out on behalf of the young person. If 12 years old, parent/guardians were asked to opt the young person in to

participating in the study by email or phone call. Participants 16+ were also provided with a parent/guardian information sheet for good practice. The researcher then had face-to-face meetings or phone calls with participants where they were able to ask any questions they had about the study. If the young person made the informed decision to take part in the study, the opportunity to provide informed consent was given. They were informed that they had the right to withdraw from the study at any point without requiring a reason and without this affecting their CAMHS treatment. In case of additional support being required or technological difficulties throughout the data collection, participants were provided with the researcher contact details.

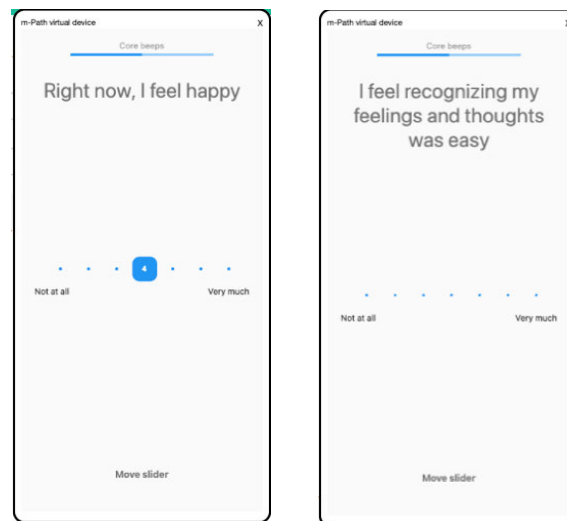
Procedure

Once consent had been provided by the young person, and the parent/guardian where necessary, an individual ID number was given to the young person to minimise the risk of data being linked to identifiable data and ensured confidentiality. Participants completed a demographic questionnaire and a trauma checklist via the Qualtrics survey platform. Young people were verbally instructed throughout the process of downloading and setting up m-path sense app on their personal phone for the study. Once the app was downloaded, participants entered their unique identifier number into their 'nickname' on the app, and then entered the practitioner code so the researcher could be linked to their account and be able to set up their ESM schedule. When their account was linked to the researcher's account, the participant trialled an ESM item to ensure they knew how to complete items on the app. Participants let researchers know of an appropriate start date for them to begin the seven-day ESM data collection. Participants provided information on their typical wake and sleep patterns, and researchers ensured that ESM items were scheduled within this. The participants received six core ESM notifications per day. The ESM items were presented through visual analogue scales or multiple-choice answers (see Figure 1). Each instance schedule was presented in the same order for each notification to reduce participant burden. Participants received a reminder prompt 15 minutes after the initial notification and had a 60-minute window to complete the brief questionnaire. Following completion of the seven-day ESM data period, participants received a debrief appointment, either in person or via the phone, to hear about their experience with this methodology and to

debrief from the study. At this time, participants could choose to receive a visual summary of their responses and receive their monetary compensation.

Figure 1

Screenshot of two questions of ESM item schedule to show item display.



Measures

Although this research aims to utilise ecological momentary assessment methodology, questionnaires were also included to gain demographic and characteristic information of the sample and to screen for trauma experiences and their self-reported impact.

Qualtrics Measures:

Demographics

Demographic data collected for each participant included date of birth, age, gender, ethnicity, and their highest level of education.

Childhood Trauma Questionnaire - Short Form – Environmental influences on Child Health Outcomes (ECHO)- Wide Cohort Version (Pennebaker and Susman, 1988).

The Childhood Trauma Questionnaire- Short Form was used as a checklist trauma screener as it identifies six categories of trauma experience in childhood up until the age of 18 and

the self-reported trauma impact per category. Categories included death, divorce/separation, sexual trauma, violence (abuse, mugging or assault), being ill/injured and 'other trauma'. This measure did not ask for further detail of reported trauma experiences. Participants were to report 'yes' or 'no' to experiencing each trauma category. They are then asked, "how traumatic was this?" using a 7-point Likert scale where 1= not at all traumatic, 4= somewhat traumatic, and 7=extremely traumatic. The average impact of trauma was averaged per participant. As experiencing trauma is not always synonymous with developing post-traumatic stress disorder symptoms, trauma experience rather than PTSD symptomology was deemed most appropriate to ensure we encapsulated those who are subthreshold for PTSD diagnoses. Current trauma measures may take an extensive length of time to complete and focus on PTSD symptomology rather than ratings of trauma exposure and impact (Dowdy-Hazlett et al., 2021). Alternative measures were considered too detail-specific and extensive and so, not appropriate to burden participants as that data would not have been utilised. Cronbach alpha (α) was 0.852, indicating good internal consistency.

Experience Sampling Methodology (ESM) Items:

Experience sampling methodology was used to explore momentary measures of mental wellbeing, mentalization and perceived social support within young people's everyday context. The ESM items presented in the current study followed a semi-random sampling scheme and included core day items presented six times daily (see Table 1). The random sampling scheme is the most used sampling scheme within ESM research as it results in a relatively high ecological validity, relatively low participant burden and thus relatively small negative consequences for compliance (Myin-Germeys and Kuppens, 2022). Momentary wellbeing ESM items were derived from the OSD ESM Item Repository (available from: <https://osf.io/5ba2c>) where researchers input items used within previous and current ongoing research studies. ESM items for momentary perceived social support and momentary mentalizing (event specific) were created for this study as a proof of concept.

Table 1

ESM Items present on every occasion.

Domain	Question	Response Option	Question Rule
Momentary Wellbeing	Right now, I feel...	1(Not at all) - 7 (Very much)	N/A
	Happy		
	Enthusiastic		
	Relaxed		
	Content		
	Anxious		
	Irritated		
	Sad		
	Insecure		
Momentary Perceived Social Support	Right now, how easily do you feel you could ask for help from someone?	1 (Not at all) - 7 (Very much)	N/A
	Right now, how easily do you feel you could receive help from someone?	1 (Not at all) - 7 (Very much)	
Momentary Mentalizing – Event Specific	Has anything important or stressful happened to you since the last beep?	Yes or No	If yes, proceed to questions. B) and C)
	B) I feel recognising my feeling and thoughts was easy	1(Not at all) - 7 (Very much)	
	C) It was easy to identify other people's feelings and thoughts	1(Not at all) - 7 (Very much)	

Statistical Analysis & Results

Sample Size

ESM results in a greater number of data points per participant compared to static measures as participants complete multiple repeated assessments over the study duration (i.e., 6 assessments per day for 7 days). As such, a relatively small sample is sufficient in statistical analyses that model within person relationships. A priori sample size estimation with the sjstats package developed for linear mixed models (LMM; Lüdtke, 2021) was conducted. Due to the lack of similar studies using ESM with similar predictor variables, this calculation was based on the effect sizes reported by another study employing ESM to investigate interpersonal risk factors. The study of interpersonal risk in adolescents during covid (Bamps et al. 2024) suggested an effect size of $d = 0.4 - 0.6$. Therefore, for alpha 0.05, power 80%, and an effect size of $d = 0.6$, the required sample size was 64 participants.

Demographic and Sample Characteristics

Demographic and sample characteristic data analysis were conducted on IBM SPSS Statistics (Version 27) and can be seen in Table 2. No participants opted to drop out of the study after providing consent; although compliance to the scheduled 42 ESM beeps (7 days of 6 beeps each day) was variable ($M = 67.4\%$, Range = 19-92%).

During debrief appointments, participants reported a range of reasons for not completing ESM instances including not being able to complete during school times despite informing teachers of study participation, their phone running out of battery during the day or leaving their phone at home accidentally. No participant reported that the schedule of ESM instances was deemed too frequent although this may have been reported differently if answered anonymously. No technical issues were reported with the ESM item scheduling delivery.

Table 2
Sample characteristics N=27

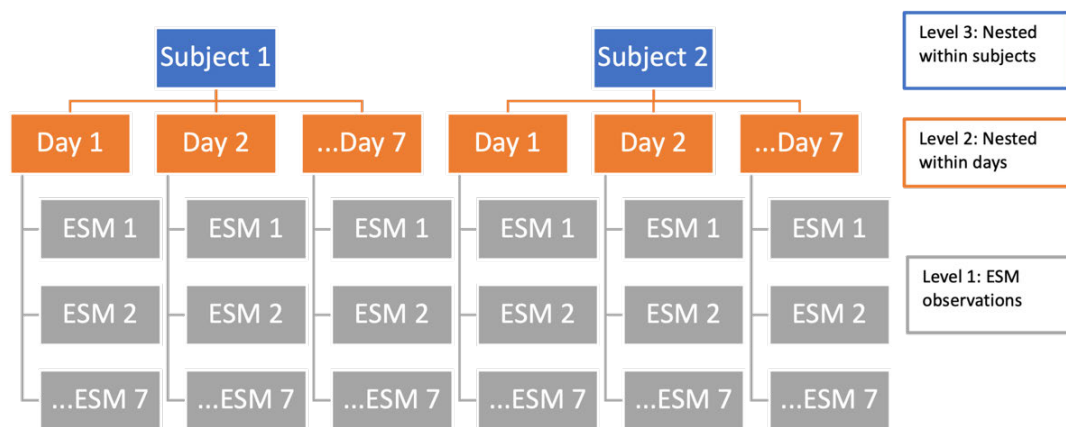
Age	Range = 12-18 years old M= 16.4 (SD= 1. 6)	
Gender		
Female	N= 21 (78%)	
Male	N= 6 (22%)	
Ethnicity		
White: Scottish	N= 20 (74%)	
White: Polish	N= 1 (3%)	
White British Other	N= 1 (3%)	
Middle Eastern	N= 1 (3%)	
Indian	N= 1 (3%)	
Mixed or multiple ethnic groups	N= 4 (14%)	
Education level to date		
S1	N= 2 (7.4%)	
S2	N= 1 (3.7%)	
S3	N= 3(11.1%)	
S4	N= 7(25.9%)	
S5	N= 4 (14.8%)	
S6	N= 4 (14.8%)	
College	N= 6 (22.2%)	
Trauma Experience		
Death – friend/family	Yes: 14 (52%)	No: 13 (48%)
Parents- divorce/separation	Yes: 10 (37%)	No: 17 (63%)
Sexual abuse trauma	Yes: 10 (37%)	No: 17 (63%)
Physical abuse trauma	Yes: 8 (30%)	No: 19 (70%)
Ill/ injured	Yes: 5 (18.5%)	No: 22 (81.5%)
Other	Yes: 14 (52%)	No: 13 (48%)
Average number of trauma types experienced:	2.22 (SD= 1.25), Range= 1-5	
Average trauma impact:	4.38 (SD= 1.12) Range = 2-6.4	
ESM Measure Compliance	Response Rate M= 67.4% (SD=21.8)	
Total (N=27):	Response Range: 19-92%	
Females (N=21)	M: 45.8% (SD= 5.1) (Range: 19-92%)	
Males (N=6):	M: 76.3% (SD= 5.2) (Range: 53-86%)	

Multilevel Modelling

ESM data have a hierarchical structure whereby multiple ESM observations (Level 1) are nested within days (Level 2), and then further nested within participants (Level 3); see Figure 2). Multilevel modelling (MLM) is typically used when examining ESM data that holds a nested hierarchical structure and allows the assessment of variation in variables at several levels simultaneously (e.g., the variations between groups and individuals). The MLM method is well-suited over the conventional ordinary least squares (OLS) regression approaches in this instance as MLM can effectively accommodate the dependency among Level 1 data and manage uneven time-intervals between responses and variations in the number of responses across participants (Chen et al., 2023). This assists in ESM data's statistical power for detecting the effects (Bell et al., 2014; Chen et al., 2016). Moreover, MLM can manage missing data well as it is assumed to be missing at random. For the analyses, a p -value of less than 0.05 was determined to be statistically significant.

Figure 2

Visual representation of nested multi-level model data structure



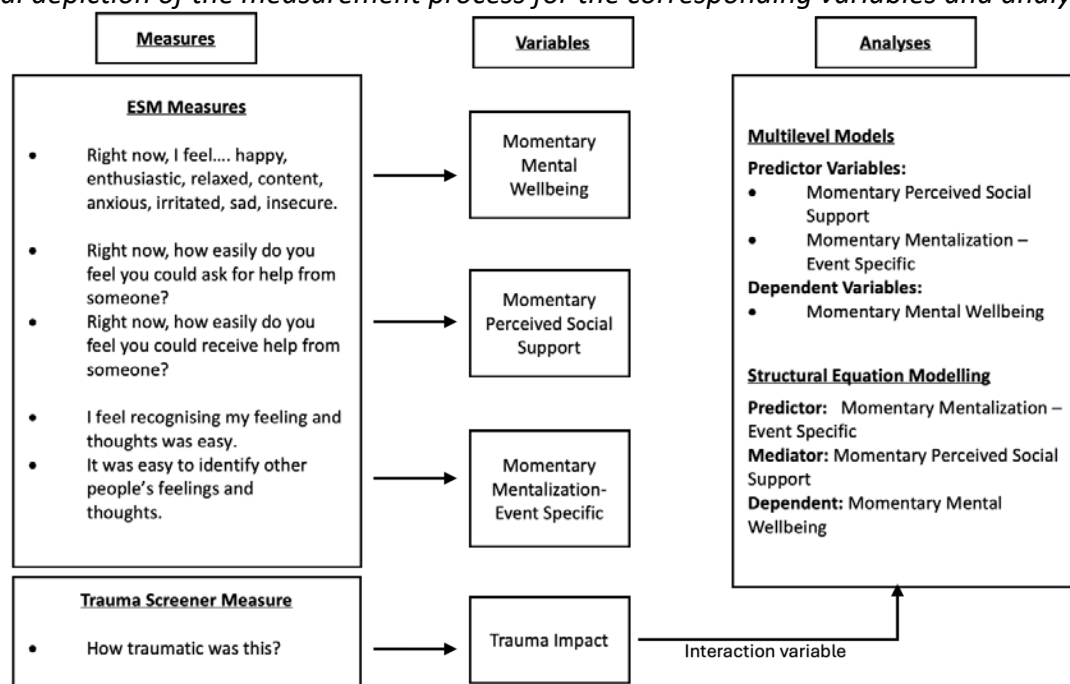
Multi-level modelling (MLM) analysis was conducted on the statistical package 'R' (R Core Team, 2023) with additional installed packages including 'lme4', 'nlme', 'lmerTest', 'mediation', 'ggplot2', 'sjstats', 'reshape2', 'lavaan'. The 'lmer' package within the 'R' statistical package was used to conduct the linear mixed models (R Core Team, 2023). Raw data was represented to a long format prior to analyses. Missing data is managed well within multilevel modelling, as the MLM does not assume an equal number of occasions or fixed time points, thus all cases can be used for analysis.

A model building approach helps to inform the understanding of how groups of predictors relate to each other. As such, this approach was utilised to allow the examination of how time and day variance are influenced by the introduction of additional predictors. Following this, to answer the research question of how momentary perceived social support mediates the relationship between momentary mentalization and mental wellbeing for children and young people who have experienced trauma in the context of their daily lives, structural equation modelling (SEM) was conducted. SEM can manage longitudinal designs well and has greater statistical power due to SEM statistics being more sensitive (Beran and Violato, 2010). Due to risks of multicollinearity with the two ESM items that created the average mentalization variable, multi-level analysis will focus on the mentalizing of other variable independently.

It was hypothesised that greater momentary mentalization and momentary perceived social support scores will positively predict momentary mental wellbeing for trauma experienced adolescents who are seen within CAMHS. Moreover, it was hypothesised that perceived social support would mediate the relationship between momentary mentalization and momentary mental wellbeing. Figure 3 depicts the measurement process and the corresponding variables and analyses.

Figure 3

Visual depiction of the measurement process for the corresponding variables and analyses.



Tests of Assumptions

Multilevel models assume normality, linearity, homogeneity of variance and independence of observations. Homogeneity of variance and linearity assumptions were met. The assumption of normality was tested visually through a histogram, as well as by conducting a Shapiro-Wilk test. The test showed that the distribution of mental wellbeing departed significantly from normality ($W = 0.962, p < 0.01$), and was negatively skewed. Thus, the assumption of normal distribution was not met. To address the underpowered sample and the assumption violation, a bootstrapping approach was conducted in the analysis.

Analysis

RQ 1: Momentary Mentalization: *Does momentary event specific mentalization predict momentary wellbeing for trauma experienced children and young people?*

The linear regression with momentary mental wellbeing as the outcome variable revealed that the predictor average event specific mentalizing was not significant ($\beta = -0.026, p = 0.557$). These findings suggest that the average of the two ESM momentary mentalization items reported following a stressful event did not significantly predict momentary mental wellbeing for adolescents within this sample.

As such, further exploratory analysis was conducted using a linear mixed model with one item of momentary mentalization, the event specific mentalizing of others, on the outcome variable mental wellbeing. Model 1 exploring the linear relationship between event specific momentary mentalization of others and momentary mental wellbeing indicated that the intercept was significant ($\beta = 3.845, p < 0.001$). The intercept also varied across individuals: $0.73, sd = 0.85 (t = 18.28), p < 0.001$. The model showed significant effects for event specific mentalizing of others ($\beta = -0.073, p < 0.04$). The adjusted ICC was 0.167, and so 16.7% of the variance in momentary mental wellbeing can be explained by momentary mentalization.

Model 2 added the interaction term of average trauma impact into the modelling. Results can be seen in Table 3. For the final multilevel model for momentary mental wellbeing, the standardised scaled residuals were -2.6360 to 2.1233 . The adjusted ICC was 0.156, indicating 15.6% of the variance in momentary mental wellbeing could be explained by the

predictor variables momentary mentalization and average trauma impact. The intercept was significant ($\beta = 3.985$, $p < 0.001$) and varied across individuals: 0.68 $sd = 0.826$ ($t = 4.498$, $p < 0.001$). The multilevel model findings indicated that the event specific mentalizing of others had a significant negative effect on momentary mental wellbeing ($\beta = -0.369$, $p = 0.0348$). The interaction of event specific mentalizing of others and average trauma impact was approaching significance ($\beta = 0.035$, $p = 0.067$). The interaction of average trauma impact and average mentalizing event specific did not indicate a significant effect ($\beta = 0.017$, $p = 0.66$). The average mentalizing event specific ($\beta = -0.077$, $p = 0.658$) and the average trauma impact ($\beta = -0.029$, $p = 0.879$) did not show significant effects, indicating that they did not influence the momentary mental wellbeing in the sample.

This indicates that within this model, there was a negative relation between the event specific mentalization of others, and momentary mental wellbeing. A unit increase in the mentalization of others would lead to a 0.369 decrease in participants' momentary mental wellbeing. Moreover, as the interaction of mentalization of others and average trauma impact approached significance, it could indicate that there could be a potential significant relation between of these interaction terms. Whereby, one unit increase in the interaction effect, would lead to a 0.067 increase in momentary mental wellbeing.

Table 3

Multilevel Model for Momentary Mental Wellbeing, with trauma interaction

	β	SE	t	p
Intercept	3.985	0.8866 4	4.498	0.001***
Mentalizing of Others - Event Specific	-0.369	0.174	-2.116	0.0348 *
Average Trauma Impact	-0.029	0.196	-0.152	0.879
Mentalizing of Others- Event Specific *Average Trauma Impact	0.067	0.038	1.734	0.083
Average Trauma Impact * Average Mentalization – Event Specific	-0.017	0.041	0.427	0.669

Note. β = fixed regression coefficient, SE= standard error, * $p < 0.05$, ** $p < 0.01$, *** $p > 0.001$

RQ 2: Momentary Perceived Social Support: *Does momentary perceived social support (MPSS) predict momentary wellbeing for trauma experienced children and young people?*

Model 1 explored the relationship between momentary perceived social support and momentary mental wellbeing. Standardised scaled residuals were -3.7671 to 3.5363 . Model 1 indicated that the intercept was significant ($\beta = 1.147, p < 0.001$) and varied across individuals: $0.11, sd = 0.34$ ($t = 7.03, p < 0.001$). Momentary perceived social support ($\beta = 0.699, p < 0.001$) was also significant. The adjusted ICC for this model was 0.295 , indicating that 29.5% of the variance in momentary mental wellbeing could be explained by momentary perceived social support.

Model 2 (as shown in Table 4) introduced the trauma impact interaction term into the multi-level regression model with momentary mental wellbeing as the outcome variable. The standardised scaled residual was -4.1051 to 4.0553 . The model showed that the intercept ($\beta = 1.130, p = 0.116$) was no longer significant. The intercept did not vary across individuals: $0.58, sd = 0.76$ ($t = 1.614, p = 0.116$). Momentary perceived social support ($\beta = 0.680, p < 0.001$) remained significant. However, the average trauma impact ($\beta = -0.001, p = 0.993$) and the interaction between momentary perceived social support and the average trauma impact ($\beta = 0.007, p = 0.730$) were not significant. The adjusted ICC was 0.270 indicating that 27% of the variance of momentary mental wellbeing could be explained by the predictor variables, momentary perceived social support and average trauma impact.

These findings suggest that momentary perceived social support had a positive relation with momentary mental wellbeing, whereby one unit increase in momentary perceived social support would lead to a 0.680 unit increase in momentary wellbeing.

Table 4*Multilevel Model for Predictor MPSS and Momentary Mental Wellbeing*

	β	SE	t	p
Intercept	1.130	0.700	1.614	0.116
Momentary Perceived Social Support	0.680	0.094	7.193	0.001***
Average Trauma Impact	-0.001	0.155	-0.009	0.993
Momentary Perceived Social Support x Average Trauma Impact	0.007	0.020	0.345	0.730

Note. β = fixed regression coefficient, SE= standard error, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

RQ 3: Is there an interaction between mentalization and perceived social support for trauma experienced children and young people?

To assess the interaction between mentalization and perceived social support within the sample models were conducted. Model 1 explored the predictors average mentalising-event specific- and momentary perceived social support. The standardised scaled residuals for the model were -3.8104 to 3.9584 . For this model, the intercept ($\beta = 1.165$, $p < 0.001$), average event specific mentalizing ($\beta = -0.159$, $p < 0.001$) and momentary perceived social support ($\beta = 0.727$, $p < 0.001$) were significant. The intercept also varied across participants: 0.48 , $sd = 0.69$ ($t = 7.359$, $p < 0.001$). The adjusted ICC for this model was 0.240 indicating that 24% of the variance could be explained.

Model 2 then explored the interaction effect of two predictor variables: event specific average mentalizing and momentary perceived social support. The standardised scaled residuals were -3.6262 to 4.1214 . The adjusted ICC was 0.242 , indicating that 24.2% of the variance was explained. The fixed effects model indicated that the intercept ($\beta = 1.055$, $p < 0.001$) was significant and varied across individuals: 0.46 , $sd = 0.68$ ($t = 6.722$, $p < 0.001$). The model also indicated that average mentalizing event specific ($\beta = 0.255$, $p < 0.001$), momentary perceived social support ($\beta = 0.752$, $p < 0.001$), and the interaction of average mentalizing event specific and momentary perceived social support ($\beta = -0.098$, $p < 0.001$), was significant.

Model 3, the final model seen in Table 5, then added in the interaction effect of average trauma impact to the model. The scaled residuals for the model were -3.6096 to 4.1025 . The adjusted ICC 0.256 , indicating that that 25.6% of the variance of mental wellbeing could be explained by momentary mentalization and momentary perceived social support. Within the multilevel model (see Table 5), the intercept was not significant ($\beta = 1.055$, $p = 0.118$) and so did not vary across participants: 0.504 , $sd = 0.71$ ($t = 1.601$, $p = 0.118$). The model also indicated that average event specific mentalizing ($\beta = 2.567$, $p < 0.001$), and momentary perceived social support ($\beta = 7.801$, $p < 0.001$), showed significant effects. The interaction of event specific average mentalizing and momentary perceived social support indicated significant effects ($\beta = -9.856$, $p < 0.001$). However, average trauma impact ($\beta = -2.701$, $p = 0.998$) and the interaction of momentary perceived social support and average trauma impact ($\beta = -5.959$, $p = 0.6768$) did not reach significance levels of effects.

Table 5

Multilevel Model for Mentalization, Perceived Social Support & Trauma Impact Interaction

	β	SE	t	p
Intercept	1.055	6.588	1.601	0.118
Average Mentalization- Event Specific	2.567	7.405	3.466	0.001***
Momentary Perceived Social Support	7.801	9.210	8.470	0.001***
Average Trauma Impact	-2.701	1.466	-0.002	0.998
Momentary Perceived Social Support * Average Mentalization Event Specific	-9.856	1.621	-6.080	0.001***
Momentary Perceived Social Support * Average Trauma Impact	-5.959	2.020	-0.295	0.768

β = fixed regression coefficient, SE= standard error, * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$

The findings indicate that the interaction of momentary perceived social support and average mentalization had significant relation to momentary mental wellbeing with a large effect size of 9.856 , indicating that there is an additive effect with both mentalization and perceived social support.

RQ 4: In the context of their daily lives, how might perceived social support mediate the relationship between wellbeing and mentalization for CYP attending CAMHS?

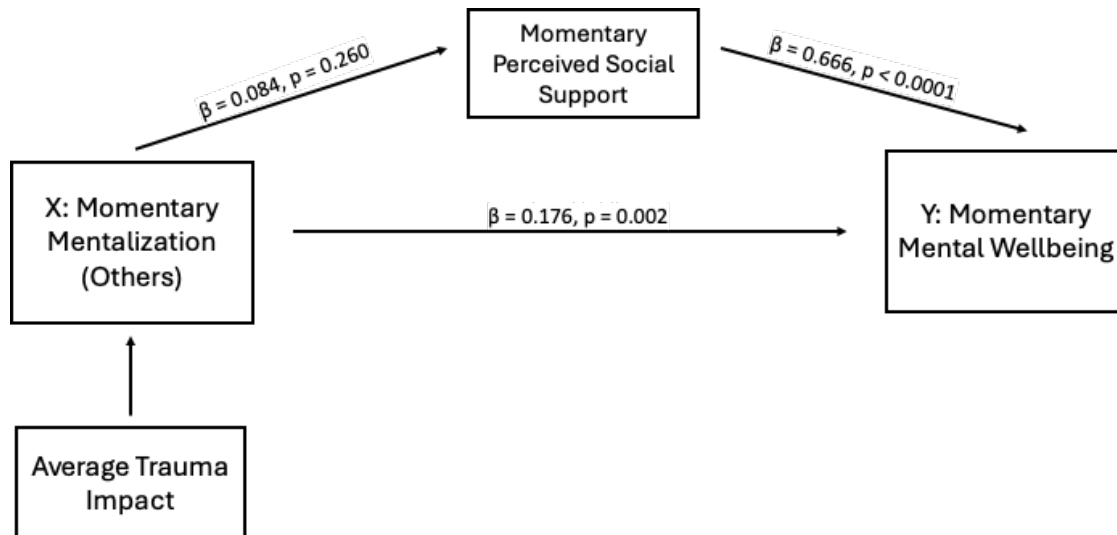
Mediation analyses, with structural equation modelling (SEM), was performed using the lavaan package in R on three occasions to investigate the mediation model with different mentalization variables (the average mentalization and the mentalization of others), and with further paths. Mentalization with trauma impact interaction variable, momentary perceived social support and mental wellbeing were latent variables in the model. Model 1, as seen in Figure 4, specifies one direct path from momentary mentalization to momentary mental wellbeing and an indirect path from momentary mentalization to mentalisation through momentary perceived social support.

Standardised estimates (between -1 and 1) were reported rather than raw estimates, so that estimates from different structural equations re on the same scale, simplifying interpretation. The model showed excellent model fit according to multiple SEM fit statistics and indices: $\chi^2(3) = 703.715$, $p < .0001$; Root Mean Square Error of Approximation (RMSEA) for both upper and lower 90% confidence interval was 0.0001 , Comparative Fit Index (CFI)= 1.0 ; Tucker-Lewis Index (TLI)= 1.0 . Guidance suggests that CFI ≥ 0.95 , TLI ≥ 0.95 and RMSEA ≤ 0.05 represent a good fitting model (Gunzler, Chen, Wu et al., 2013). Akaike's Information Criteria (AIC) and Bayesian Information Criteria (BIC) provide a unit to compare goodness of model fit between models Lower AIC or BIC values suggest a better fit. For the model, AIC = 9711.353 and BIC = 9740.053 .

The path diagram (Figure 4) of the mediation model includes the standardised estimates for both the paths for the indirect and direct effects. As shown in the path diagram, not all individual paths were significant. Momentary mental wellbeing was associated with momentary mentalization ($\beta = 0.176$, $p < 0.002$). Momentary mental wellbeing was associated with perceived social support ($\beta = 0.666$, $p < 0.0001$). Momentary perceived social support was not associated with momentary mentalization ($\beta = 0.084$, $p < 0.260$).

Figure 4

Path diagram of the mediation of momentary perceived peer support on the relationship between momentary mentalization of others and momentary mental wellbeing, including the trauma interaction.



The direct effect of momentary mentalization of others and momentary mental wellbeing was not significant ($\beta = 0.056, p = 0.261$). However, the indirect effect of momentary perceived social support on the relation between momentary mentalization and momentary mental wellbeing was significant ($\beta = 0.232, p < 0.001$).

These findings indicate that when measured independently, the momentary mentalization of others was associated with momentary mental wellbeing. When measured within the full mediation model, the direct relation of momentary mentalization of others to momentary mental wellbeing is not significant. Whereas the indirect mediation effect of momentary perceived social support is associated significantly with children and young people within this samples' momentary mental wellbeing.

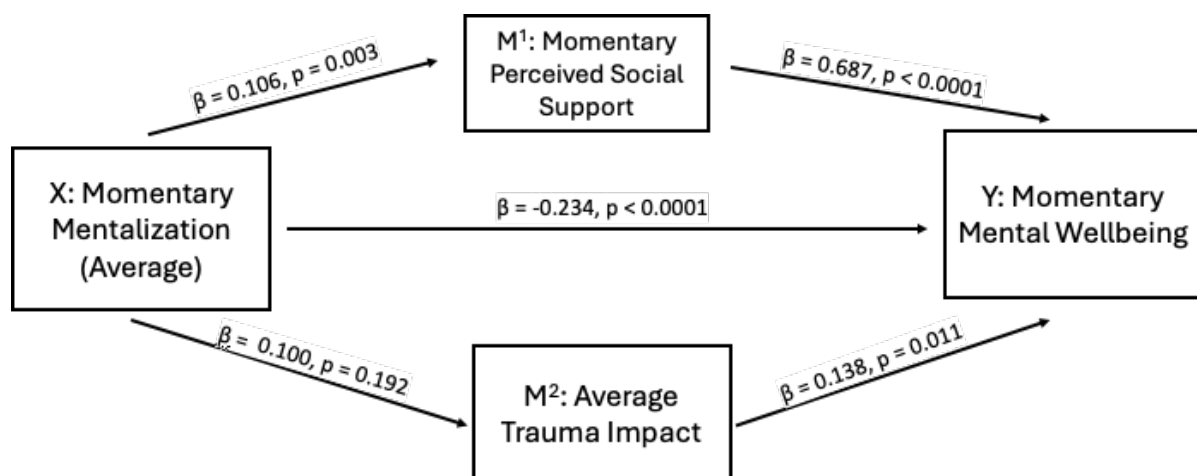
SEM Model 2:

Model 2 seen in Figure 5 explored the mediation relationship of momentary perceived social support between average momentary mentalization and momentary mental wellbeing. Path analysis was conducted to explore the relationship between the predictor average trauma impact and mediator momentary perceived social support, and between the dependent variable momentary mental wellbeing. The model showed excellent model fit according to multiple SEM fit statistics and indices: $\chi^2(6) = 780.022$, $p < 0.0001$; Root Mean Square Error of Approximation (RMSEA) for both upper and lower 90% confidence interval was 0.000, Comparative Fit Index (CFI)= 1.0; Tucker-Lewis Index (TLI)= 1.0. The AIC = 12986.206 and BIC = 13034.039.

As shown in the path diagram, momentary mentalization was negatively associated with momentary mental wellbeing ($\beta = -0.234$, $p < 0.0001$), and was not associated with average trauma impact ($\beta = 0.100$, $p = 0.192$). Momentary mentalization was positively associated with momentary perceived social support ($\beta = 0.106$, $p = 0.003$). Momentary perceived social support was also positively associated with momentary mental wellbeing ($\beta = 0.678$, $p < 0.0001$). Average trauma impact was also associated with momentary mental wellbeing ($\beta = 0.138$, $p < 0.011$).

Figure 5

Path diagram of the mediation process of momentary perceived social support on the relationship between average momentary mentalization and momentary mental wellbeing, and the mediation process of momentary perceived peer support on the relationship between average trauma impact and momentary mental wellbeing.



For the mediation of momentary perceived social support between average momentary mentalization and momentary mental wellbeing, the direct effect was significant ($\beta = -0.162$, $SE = 0.033$, $p < 0.0001$); the indirect effect from mentalization to momentary mental wellbeing was also significant ($\beta = 0.072$, $SE = 0.024$, $p = 0.003$). For the mediation of average trauma impact between momentary mentalization and momentary mental wellbeing, the direct effect was significant ($\beta = 0.206$, $SE = 0.066$, $p = 0.002$). However, the indirect effect with average trauma impact as a mediator from momentary mentalization to momentary mental wellbeing was not significant ($\beta = 0.068$, $SE = 0.052$, $p = 0.193$). Analysis on the effects of differential paths were conducted and found that the differential paths of the mediators were not significant ($\beta = 0.004$, $SE = 0.054$, $p = 0.0946$) indicating that the mediation paths were not significantly different than the other.

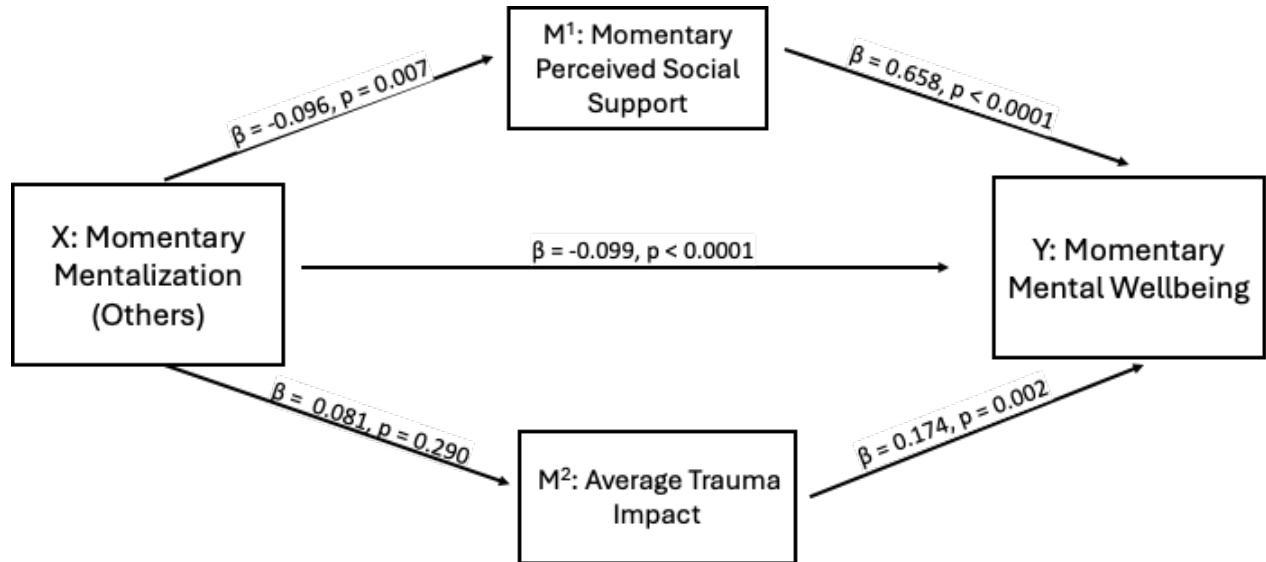
SEM Model 3: Further Path Analysis

SEM Model 3, seen in Figure 6, explored the mediation relationship of momentary perceived social support and average trauma impact between momentary mentalization of others and momentary mental wellbeing. Further path analysis was conducted to explore the relationship between mentalization, average trauma impact and momentary perceived social support, and between momentary mental wellbeing. The model showed excellent model fit according to multiple SEM fit statistics and indices: $\chi^2(6) = 732.653$, $p < 0.0001$; Root Mean Square Error of Approximation (RMSEA) for both upper and lower 90% confidence interval was 0.001, Comparative Fit Index (CFI) = 1.0; Tucker-Lewis Index (TLI) = 1.0. The AIC = 13614.393 and BIC = 13662.226 for the model.

As shown in the path diagram (Figure 6), momentary mentalization of others was negatively associated with momentary mental wellbeing ($\beta = -0.084$, $p < 0.0001$), and average trauma impact ($\beta = -0.164$, $p < 0.0001$), and momentary perceived social support ($\beta = -0.110$, $p < 0.001$). Momentary perceived social support was associated with momentary mental wellbeing ($\beta = 0.689$, $p < 0.0001$). Average trauma impact was also associated with momentary mental wellbeing ($\beta = 0.078$, $p < 0.001$).

Figure 6

Path diagram of the mediation process of momentary perceived social support on the relationship between momentary mentalization of others and momentary mental wellbeing, and the mediation process of average trauma impact on the relationship between mentalization and momentary mental wellbeing.



For the mediation of momentary perceived social support between momentary mentalization of others and momentary mental wellbeing, the direct effect was significant ($\beta = -0.163$, $SE = 0.031$, $p < 0.001$); the indirect effect was also significant ($\beta = -0.063$, $SE = 0.024$, $p = 0.008$). For the mediation of average trauma impact between momentary mentalization of others and momentary mental wellbeing, the direct effect was significant ($\beta = 0.228$, $SE = 0.066$, $p = 0.001$). However, the indirect effect was not significant ($\beta = 0.053$, $SE = 0.050$, $p = 0.290$).

Analysis on the effects of differential paths were conducted and found that the differential paths of the mediators were significant ($\beta = -0.117$, $SE = 0.054$, $p = 0.032$) indicating that the mediation paths were significantly different from each other.

Discussion

Many research studies utilise static questionnaire formats to investigate mentalization despite the theoretical background suggesting that mentalization is dynamic in nature and dependent on contextual factors (Fonagy et al., 2012). This proof-of-concept study aimed to address the current gaps in research by utilising experience sampling methodology via digital means to gain an understanding of the relationship between momentary event specific mentalization on the momentary mental wellbeing of children and young people in CAMHS in Scotland in their everyday social context. The study also aimed to investigate the mediating role of momentary perceived peer support on momentary mental wellbeing.

In contrast with the first hypothesis, average momentary mentalization was not found to have a significant relation with momentary mental wellbeing for children and young people. therefore, further exploratory analysis was conducted. In contrast to the initial hypothesis of the study, momentary mentalization of others was found to have a negative significant association with momentary mental wellbeing. This finding contrasts with extant literature that suggests that the ability to understand one's own and others' minds is a key factor for mental wellbeing. Bellepsi et al. (2021) found that in a school adolescent sample the mentalization of others' mental states was associated with all measures of functioning (i.e., general, social and role functioning) and was associated with participants' happiness. It would be interesting to explore whether this difference is related to the measurement method, the participant sample (clinical vs non-clinical sample) or if there were other factors at play such as a sensitised awareness or perceived criticism of the minds of others. For example, although participants may be indicating a greater mentalizing of others, they may be perceiving this as negative which negatively impacts their mental wellbeing. Additionally, further research should be conducted to consider whether this finding is consistent with further CAMHS participant samples that have not experienced trauma.

Secondly, consistent with the second hypothesis, momentary perceived social support was found to be significantly positively related to momentary mental wellbeing with a large effect size for children and young people within the sample. Previous literature has shown that perceived social support has a positive impact on participant's momentary mood. There is no current research highlighting this within a clinical adolescent population. However,

Smyth et al. (2014) reported a stress buffering effect that more perceived social support resulted in fewer reported symptoms when stress was present and that this directly related to better ambulatory status for adult patients with arthritis and/or asthma. Potter (2023) explored the moderating effect of momentary perceived social support on mental resilience and positive and negative affect. The study findings suggested that there was a significant direct effect on mental resilience on negative and positive effect only when participants had moderate levels of momentary perceived social support. In a meta-analytic review on the association between perceived social support and depression in childhood and adolescence, Rueger et al., (2016) reported that there were different patterns of effect sizes and that these varied across different types of support (i.e., parent, friend, other) on measures of depression in the samples. They also reported that different stressful contexts may not allow young people to fully draw on the benefits of social support. This further supports the importance of exploring social support across time and context.

Research question three, whether there was an interaction between momentary mentalization and momentary perceived social support for trauma experienced children and young people was also proven to be significant. The results indicated an additive effect indicating that both mentalization and perceived social support are both independently and combined important factors that impacts the mental wellbeing of adolescents who have experienced trauma. To the best of my knowledge, there is no current research that explored this interaction between momentary mentalization of others and momentary perceived social support. However, previous literature has shown the individual impact these variables have on mental wellbeing for children and young people on a time-static basis as discussed previously.

Lastly, the mediating role of momentary perceived social support and the average trauma impact were explored through three separate structural equation models (SEM). SEM Model 1 indicated that when observing independently, both momentary mentalization of others and momentary perceived social support were significantly associated with momentary mental wellbeing. However, momentary perceived social support was not associated with momentary mentalization of others. When the model is tested in full, the direct effect of momentary mentalization of others on momentary mental wellbeing is not

significant, but the indirect effect remains significant. SEM Model 2 used the average momentary mentalizing in the mediation model. This indicated that the mediation of momentary perceived social support between average momentary mentalization and momentary mental wellbeing showed a significant effect for the direct and indirect effect. Moreover, the mediation of average trauma impact between momentary mentalization had a significant direct effect, but a non-significant indirect effect. The mediation of both momentary perceived social support and the average trauma impact were shown to not be significantly different. SEM Model 3 used the momentary mentalization of others within the double mediation model. The mediation of momentary perceived social support between mentalization and momentary wellbeing showed a significant direct and indirect effect. The mediation of average trauma impact between mentalization and momentary mental wellbeing indicated a non-significant indirect effect, but a significant direct effect. These models indicate that the mentalization of others had a significant association with momentary mental wellbeing. Thus, the mentalization of others is a key factor associated with mental wellbeing in children and young people in this sample. Additionally, these results suggest that for trauma-experienced children and young people in this sample, momentary perceived social support and the average trauma impact are also a key mediational factor associated with momentary mental wellbeing.

Limitations

As a proof-of-concept study and the first to explore the mentalization of adolescents in Scotland in their everyday context, acknowledging the limitations of the present study is important for future research considerations. The participant sample for this study was relatively small although similar in size to other research with an ESM approach. Moreover, the sample was primarily female (73%). As such, the sample is not representative of the experience for all genders within mental health services and so the findings cannot be fully generalised to derive further meaning. However, this may reflect the higher prevalence rates for female (22%) adolescents compared to males (18.8%; NHS Digital, 2020).

Regarding ESM methodology, to reduce participant burden, ESM observations were set up in collaboration with and according to the participant's schedule and availability. For example, if a young person felt unable to respond to a prompt due to attending a club or

their school did not allow phones during school time, they could suggest that the semi-random sampling time frame be adjusted to suit. This likely will have resulted in ESM beeps occurring in a reduced range of environments and context for some participants that amended their ESM schedule, thus reducing the understanding of the contextual fluctuation of momentary mentalization, perceived peer support and mental wellbeing. Additionally, ESM instances were scheduled to have a 60-minute window for completion, and a 15-minute prompt reminder following the initial beep. Although this allows participants to respond to a greater extent, it may mean that there is more chance of recall bias occurring. However, as the questions asked in ESM are in the moment, it is likely that the participant still answered these assessments in the moment rather than reflecting on events. Further detailed information gathering for each ESM instance for each participant, such as the completion duration of the instance (e.g., completed in under 10 seconds vs 2 minutes) and the level of fluctuation in responses (e.g., answering same answer for every instance vs fluctuation in answers) could help explore potential limitations of ESM. For example, if it is understood that on an individual level, a participant was answering responses unreasonably quickly and with no fluctuation in answers, it could be suggested that they were completing instances inaccurately and therefore not compliant to the ESM procedure. Despite attempts to reduce participant burden, compliance rates within the sample were significantly varied (19-92%) despite the average compliance rate of 65.18% being like rates observed in other studies. Although there is no gold-standard in relation to compliance rate, promoting participant compliance is critical (Heron, Everhart, McHale et al., 2017). Integrating compliance-contingent participant compensation for participation could increase the response rates.

Regarding the mentalization items utilised for this study. It would be important to validate these further to ensure they are measuring what we consider to be mentalization within this study. This could be considered by comparing and validating the items by comparing with static questionnaire items. Furthermore, the Childhood Trauma Questionnaire was used as a trauma checklist for the study although it is not a validated questionnaire. This measure was used to gain an understanding of the number of trauma types experienced and the perceived impact of these. Many alternative measures ask participants to answer questions on their experience of trauma through detailed and explicit questions. It was felt

to be unnecessarily burdensome and unethical for young people to complete questions in relation to this for the purpose of this study as it was not possible to explore these factors in detail due to not having sufficient power to investigate different categories of trauma experiences within analyses. A validated trauma screener with evidence of good psychometric properties that allows participants to identify the types of trauma experiences they have had whilst also reporting the perceived impact of these would be beneficial for future research.

Research and Clinical Implications

This research aimed to explore key factors that have been individually shown to be associated with the mental wellbeing of children and young people in a non-clinical and clinical population when using time-static measurement tools. This is one of the first studies to explore these variables within a help-seeking trauma-experienced CAMHS population. Moreover, it is further novel due to its use of experience sampling methodology (ESM). These findings could have an impact in how future studies exploring the mentalization capacity of children and young people as it explored this within the context of the individual and when triggered by a self-reported stressful event. It could be possible for this to be combined with participants utilising wearable devices to measure heart rate and/or galvanic skin responses. Clinically, this research highlights that interventions that explore and focus on one's mentalizing are important to consider when working with trauma-experienced children and young people. Moreover, findings from this study further highlight the importance of the quality of the perceived support around children and young people. This study highlights that there is a strong positive effect on trauma-experienced mental wellbeing when they perceive that they can ask for and receive help from individuals in their network. This study did not explore different types of relationships such as friends, family or other important individuals but gaining a fuller understanding of what type of perceived support is most associated with mental wellbeing would help further inform intervention plans. This indicates that as well as targeting interventions around supporting to build the mentalising capacity for children and young people when under stress, clinicians and people around the young person should help to build a supportive network around the young person but also help the young person identify supports who are already present in their lives.

Conclusions

This proof-of-concept study is one of the first to explore mentalization, the impact of trauma and the mediating effect of perceived peer support on the mental wellbeing of a sample of help-seeking young people who have experienced trauma attending CAMHS, all within a momentary, time variant and contextually sensitive methodology. Although further research is needed to investigate the relationship with a larger and more powerful sample size, the study has provided preliminary evidence that momentary mentalization and the mediating role of perceived social support are important factors in the moment-to-moment mental wellbeing of children and young people who have experienced trauma. Given the high prevalence of experiencing traumatic events in childhood, further exploration of the key psychological mechanisms, like mentalization and perceived social support, utilising a time-variant and sensitive methodology would be valuable for research and practice.

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Appendices

Appendix 1 – IRAS Approval

7/28/23, 12:35 PM

Email - Simona Di Folco - Outlook

IRAS 291852. Amendment

no-reply-IRAS <no-reply-iras@hra.nhs.uk>
Wed 12/7/23 17:29
To: Simona Di Folco <Simona.DiFolco@ed.ac.uk>

This email was sent to you by someone outside the University.
You should only click on links or attachments if you are certain that the email is genuine and the content is safe.

IRAS Project ID: 291852
Sponsor amendment reference: Amendment 3

Thank you for submitting your study amendment. In accordance with the outcome of your completed amendment tool, this amendment requires no further regulatory review. Please now share this amendment with your UK research sites, in accordance with the instructions in your completed amendment tool.

For studies with more than one UK research site, your amendment will now be automatically shared with the R&D offices of any NHS/HSC research sites in Scotland and Northern Ireland, but you should share the amendment by email directly with those Research team/s.

For all NHS research sites in England and Wales, please now share this amendment by email directly with those sites, including both the R&D offices and research teams.

Do not reply to this email as this is an unmonitored address and replies to this email cannot be responded to or read.

This message may contain confidential information. If you are not the intended recipient please inform the sender that you have received the message in error before deleting it. Please do not disclose, copy or distribute information in this e-mail or take any action in relation to its contents. To do so is strictly prohibited and may be unlawful. Thank you for your co-operation..

Appendix 2 – R&D Approval

University Hospitals Division



Queen's Medical Research Institute
47 Little France Crescent, Edinburgh, EH16 4TJ

22nd October 2021

Ms Emma Martin
 Trainee Clinical Psychologist
 Psychology Department
 Mackinnon House (2nd Floor)
 Morningside Terrace
 Edinburgh
 EH10 5HF

Research & Development
 Room E1.10
 Tel: 0131 242 3330
 Email: accord@nhslothian.scot.nhs.uk

Director: Professor Alasdair Gray

Dear Ms Martin

CALDICOTT APPLICATION: CRD21063

An IG/IT security risk assessment has been undertaken on your study. Sign-off under the delegated Caldicott authority within R&D has been granted on the basis that various conditions are met.

Title of project / proposal	Investigating psychological predictors of distress and mechanisms of change in mental health treatment in adolescents
Reference:	R&D No: 2021/0064 IRAS No. 291852 REC No. 21/ES/0043
Systems capturing or storing Patient identifiable or personal information	KU LEUVEN R&D (App used for data collection)
Approved:	22 nd October 2021
Conditions of Approval: - Participants need to be aware that their data will be stored by an external company (KU LEUVEN R&D) based in Belgium. Amendment to the study Participant Information Sheet and Consent Form is required. - Data Processing Agreement (DPA) required to be in place between the Sponsor and KU LEUVEN R&D. - All software used in the project (inc embedded) to be supported for the full lifecycle of the application. - Security patches to be installed within 14 days, as per Cyber Essentials requirements, where the patch fixes a vulnerability with a severity the product vendor describes as 'critical' or 'high risk'. - KU LEUVEN R&D must notify NHS Lothian of any Data Loss Event relating to this project of which it becomes aware within twenty four (24) hours. - Any changes to the transfer or storage of NHS Lothian PII data, to be approved by NHS Lothian IG/IT Security. - Information Asset to be registered with Information Governance for any patient data collected and stored within NHS Lothian. http://intranet.lothian.scot.nhs.uk/Directory/eHealth/operationsandinfrastructure/InformationGovernance/Pages/InformationAssetRegister.aspx	

Please provide confirmation of acceptance of the requirements set out above.

Yours sincerely

Pavlina Yaneva McGovern
R&D Information Governance Lead

Research and Development, NHS Lothian

On behalf of: Miss Tracey Gillies, Executive Medical Director and Caldicott Guardian
for NHS Lothian

Cc:
Professor Matthias Schwannauer

Appendix 3: Research Poster

Take part in research from your phone!

We are looking to understand **day-to-day** feelings in **young people** aged **12-18** receiving care from **CAMHS**

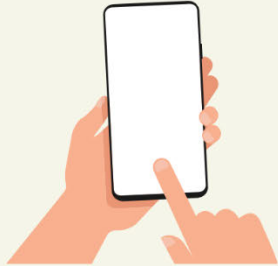
What you'll do if you take part:

1. Complete some questionnaires online
2. Use an app on your phone to answer questions about your mood and feelings

By taking part, you will:

- Help us understand youth mental health better, and by doing so, **help other young people**
- Receive monetary **compensation**
- Receive **feedback** on your participation

Want to find out more?
Scan the QR code or ask a CAMHS staff member !



THE UNIVERSITY of EDINBURGH

This study has received ethical approval from NHS Lothian, ID: 291852

Appendix 4 – Participant 12-15 Information Sheet

STUDY INFORMATION

We are inviting you to take part in a research study on young people's mental health and the treatment they receive. This sheet gives you some information about the study so that you can choose whether you want to take part or not. If there is anything else that you would like to know, or if there is something that is not clear, please speak with the clinician who you are working with in CAMHS or you can arrange to have a call with the researchers.

Why are we doing this study?

We are interested in looking at mental health in adolescents' daily lives and how young people respond to stressors. We are interested in learning about factors associated with the development and maintenance of mental health difficulties and what things change when you have treatment in CAMHS. We are also interested in looking at the impact of the covid-19 pandemic and the transition out of lockdown on young people's mental health and treatment. We would like to find out more about this by asking young people aged 12-18 to complete some online questionnaires. We would also ask you to take part in a week of data collection by downloading an app on your phone which will send you a notification several times a day and ask you to complete a short survey that takes around 60-90 seconds.

Who can take part?

You can take part if you are aged between 12-18 years old, are currently receiving treatment in CAMHS and are able and willing to take part. Your parents will also be told about this research study.

Do I have to take part?

No! It's completely up to you and choosing not to take part won't affect you in any way.

Can I change my mind?

Yes! Even if you say yes now you can decide to stop taking part at any time you want. You don't have to tell the researchers or the clinician you are working with in CAMHS

why you want to stop if you don't want to. You should note that the answers you have already given on questionnaires and the app may be used to produce reports such as journal articles and conference presentations before you withdraw and so you should contact the research team as soon as you can if you want to withdraw from the study. You can stop being part of the study at any time, without giving a reason. Deciding not to take part or withdrawing from the study will not affect your healthcare or treatment at CAMHS in any way

What does the study involve?

In this study, you will be asked to complete some online questionnaires. You will then download an app on your phone which will send you notifications at different times of the day asking you to complete a short 60-90 second questionnaire. This will take place over a week. The questions will focus on how you are feeling, what is happening and what you are doing. This helps us to get an understanding of mental health and wellbeing in your everyday life.

If you are interested in taking part, please let your clinician in CAMHS know or contact the research team using the contact details at the end of this information sheet. We will then arrange a meeting with you to answer any questions you have about the study. We will ask you to sign a consent form to show that you want to participate in the research. It's ok to say no or change your mind later on. If your parent/ caregiver decides that they would not like you to participate in this research, they can complete an opt out form meaning that you would not be able to continue with the study.

We will then show you how to download and use an app on your phone. Here is a link to the app if you would like to read a bit more about it and see what it looks like: <https://m-path.io/landing/>. During this meeting you can practice using the app and ask any questions that you have.

During this meeting, you will be asked to fill out 11 brief online questionnaires on demographics (e.g. age, gender, ethnicity) as well as mental health and wellbeing (your mood, feelings, and thoughts) at a time that works for you. Some of these questions might be a bit hard to answer, but you are welcome to leave out any questions that you don't want to answer.

You will then complete the week of data collection using the app. If any problems arise during this time, you can always get in touch with the researcher using the contact details given at the end of this information sheet.

We will ask you to carry your phone with you for a week. During that time a notification will come up on your phone multiple times a day between 7am and 10.30pm and you will be asked to fill in a short survey questionnaire about what is going on at that time, what you are doing and how you are feeling. This shouldn't take any longer than 60-90 seconds to complete. We can schedule these notifications so that they do not go off when you are in class. We can also change the time that the notifications start in the morning and stop in the evening depending on when you usually wake up and go to sleep. You can select the day that you would like to start.

If you become distressed during the questionnaires or app data collection, you can stop completing that set of questions or stop with the study entirely. If this does happen, we would encourage you to speak with your CAMHS team, a trusted adult or access support from the helplines listed at the end of this information sheet. Please note that, to ensure your safety and wellbeing, if you score on a risk related measure the researcher will inform your CAMHS team.

As well as asking you questions about how you are feeling, what you are doing and what is happening around you, the app will also collect some broad data about how you interact with your mobile phone and about your activity levels. Data will be collected on how often and for how long you use certain apps on your phone, your activity levels (e.g. step count) and how much time you spend using your phone. This allows for us to look at the relationship between social media, mobile phones and activity levels and mental health and if this changes as lockdown restrictions change. The app you will download and use on your phone will only collect data on your physical activity level and data on how long the app is open. No content from the apps on your phone will be collected.

After the week of data collection, you will be given a debrief sheet. You can also opt in to have a phone call with the researcher where you can discuss your experiences and give any feedback that you have. You will also receive your £20 voucher at this point.

When the week is over, you can look at your data and share this with the clinician you are working with if you want to. This can be helpful in your sessions. When you are finished with the study you can delete the app from your phone.

You can choose to participate in follow up data collection at the end of your treatment in CAMHS and after two years. You will be asked to complete the same set of questionnaires and data collection on the app. This allows us to see if and how things change over time. Participation in this is optional, you can let us know in the consent form if you would like to opt out of follow up data collection. If you decide that you would like to participate in follow up data collection, we would like to contact you at 6-month intervals to check if you are still being seen in CAMHS, whether you would still like to participate in follow up data collection and your contact details. We would ask that you or your clinician in CAMHS let the research team know when your treatment in CAMHS has come to an end so that we know follow up data collection can begin.

What happens if the app stops working?

Don't worry if this happens. You can contact the researcher to let them know and they will help fix this.

What are the possible benefits?

You will have access to the questionnaire data on the app. You can share this with clinician if you choose to and you could use this information in sessions. This could allow you and your clinician to have a clearer understanding of your thoughts and feelings across the week and triggers for any changes in your mood.

By taking part in this study and sharing your experience with us, you will be helping the research team to better understand the factors that influence mental health difficulties and positive treatment outcomes in CAMHS. Treatments can be developed and adapted based on this information.

You will be awarded a £20 shopping voucher as compensation for taking part in this study. You can let us know if you would like to receive this £20 voucher or not. You can still take part even if you do not want to receive the voucher. You can let us know within the online survey.

Are there any risks associated with taking part?

There are no major risks of taking part in this study. It will take a bit of time and some of the questions asked are related to your mental health. It is possible that you might find some of those questions distressing. If you do, you will be able to discuss this in sessions with the clinician you are seeing in CAMHS.

Data protection and confidentiality

The NHS will manage your identifiable information (your “personal data”) as you are participating in a study conducted by a research team working at both NHS Lothian and the University of Edinburgh. We will ask for your consent to let your GP know that you are participating in this study.

We will keep your answers private. Your data will be referred by a unique participant number rather than by name. Your data will be only viewed by the research team. We won't put your name, address or school on the survey or anything else that would mean people would know it was you. We will also store digital data on secure password-protected computers within the University of Edinburgh. The app won't store any personal identifiable information or information about our study. The responses you give on the questionnaire will be stored securely by an external company (KU Leuven Research and Development based in Belgium). If your phone gets lost or stolen, you can get in touch with the research team who can ensure that any data on the app can be deleted remotely.

We will write up the results and publish them in an academic journal. We will also share the results with your CAMHS team so you can see what we found out in the form of a generic report. We will keep personal data for 12 months after the study has finished. We will store your anonymised data for 5 years after the study has been completed.

If you disclose any information that suggests that you or someone else is at risk of harm, we will share confidential information you provided with others (e.g. the Police, the parents, social services, or other teachers) and we may need to follow the school child protection guidance to ensure safety and wellbeing. These are situations where confidentiality would have to be breached, in order to ensure that you are able to obtain support if necessary, and to ensure your safety going forward. If this was necessary, we would always try to let you know first.

How will we use information about you?

We will need to use information from you for this research project. This information will include your initials, name and contact details. People will use this information to do the research. If you consent to participating in follow up data collection at the end of your treatment in CAMHS and after 2 years, we would ask you to provide your contact details and contact details of a trusted other and ask you to update us on any changes of contact details so that we don't lose touch with you.

If you consent to participating in follow up data collection, researchers will have access to service level data on your medical records so that they know when you have been discharged from CAMHS. They will use this information to know when end of treatment data collection can be started.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your consent, your anonymised data will be uploaded to Edinburgh DataShare.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team and sending an email to contextualmh@ed.ac.uk.
- <https://www.ed.ac.uk/records-management/privacy-notice-research>

What will happen to the results of the study?

This study will be written up as theses for doctorates in Clinical Psychology and a publication that is submitted to a Peer Reviewed Journal. You will not be identifiable from any published results.

When we have finished this project, we would like to give other researchers the chance to use the anonymised data we have collected to answer their own questions. We wouldn't share any personal information about you with these researchers, like your name or your school, only questionnaire scores that people would not be able to tell was yours. You can tell us if you don't want us to share your answers with other researchers on the consent form.

If you would like to see a summary of this study's findings once the research has been completed, please tick the appropriate box on the consent form and this can be sent to you.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the East of Scotland Research Ethics Committee. NHS Management Approval has also been given.

Who can I speak to about the study?

If you have any questions about the study, you can ask the clinician that you are working with in CAMHS. If you want to get in touch with the research team directly you can speak to Connie or Sarah () or). You can also contact us via email to: contextualmh@ed.ac.uk.

If something goes wrong and you want to complain about this study, you can contact Angus Macbeth () who is the Director of Research and Knowledge Exchange, School of Health in Social Science at the University of Edinburgh.

Thank you for reading about our study!

If you would like to take part, please discuss this with your clinician in your next appointment at CAMHS or get in touch with the research team directly using the contact details provided above.



Helplines support

If you feel distressed or there are still things you may want to discuss your feelings and emotions, please contact the services listed below.

They are confidential and free helplines open 24 hours and can assist you in an emergency or crisis.

Service	Phone Number	Opening Hours	What help does it provide?
NHS 24	111	When GP is not available	Clinical health and mental health support
Edinburgh Crisis Centre	080 801 0414	24 hours	Mental health support in an emergency or crisis
The Samaritans	116 123	24 hours	Mental health support in an emergency or crisis
Mental Health Assessment Service	0131 537 6000	24 hours	Mental health support in an emergency or crisis
ChildLine Scotland	0800 1111	Anytime	Mental health support in a crisis. Help if you need someone to talk to

Breathing Space	0800 83 85 87	6pm-2am Monday to Thursday, 6pm- 6am Friday to Monday morning	Help if you are experiencing low mood or depression and need someone to talk to
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Appendix 5 – Participant 16-18 Information Sheet

STUDY INFORMATION

We are inviting you to take part in a research study on young people's mental health and the treatment they receive. This sheet gives you some information about the study so that you can choose whether you want to take part or not. If there is anything else that you would like to know, or if there is something that is not clear, please speak with the clinician who you are working with in CAMHS or you can arrange to have a call with the researchers.

Why are we doing this study?

We are interested in looking at mental health in adolescents' daily lives and how young people respond to stressors. We are interested in learning about factors associated with the development and maintenance of mental health difficulties and what things change when you have treatment in CAMHS. We are also interested in looking at the impact of the covid-19 pandemic and the transition out of lockdown on young people's mental health and treatment. We would like to find out more about this by asking young people aged 12-18 to complete some online questionnaires. We would also ask you to take part in a week of data collection by downloading an app on your phone which will send you a notification several times a day and ask you to complete a short survey that takes around 60-90 seconds.

Who can take part?

You can take part if you are aged between 12-18 years old, are currently receiving treatment in CAMHS and are able and willing to take part.

Do I have to take part?

No! It's completely up to you and choosing not to take part won't affect you in any way.

Can I change my mind?

Yes! Even if you say yes now you can decide to stop taking part at any time you want. You don't have to tell the researchers or the clinician you are working with in CAMHS

why you want to stop if you don't want to. You should note that the answers you have already given on questionnaires and the app may be used to produce reports such as journal articles and conference presentations before you withdraw so you should contact the research team as soon as you can if you want to withdraw from the study. You can stop being part of the study at any time, without giving a reason. Deciding not to take part or withdrawing from the study will not affect your healthcare or treatment at CAMHS in any way.

What does the study involve?

In this study you will complete some online questionnaires and complete a 60-90 second survey on an app on your phone multiple times a day for a week. The app will send you notifications to remind you to do this. The questions will focus on how you are feeling, what is happening and what you are doing. This helps us to get an understanding of mental health and wellbeing in your everyday life.

If you are interested in taking part, please let your clinician in CAMHS know or contact the research team using the contact details at the end of this information sheet. We will then arrange a meeting with you to answer any questions you have about the study. We will ask you to sign a consent form to show that you want to participate in the research. It's ok to say no or change your mind later on.

We will then show you how to download and use an app on your phone. Here is a link to the app if you would like to read a bit more about it and see what it looks like: <https://m-path.io/landing/>. During this meeting you can practice using the app and ask any questions that you have.

During this meeting, you will be asked to fill out 11 brief online questionnaires on demographics (e.g. age, gender, ethnicity), mental health and wellbeing at a time that works for you. Some of these questions might be a bit hard to answer, but you are welcome to leave out any questions that you don't want to answer.

You will then complete the week of data collection using the app. If any problems arise during this time, you can always get in touch with the researcher using the contact details given at the end of this information sheet.

We will ask you to carry the phone with you for a week. During that time a notification will come up on your phone multiple times a day between 7am and 12pm and you will be asked to fill in a short survey questionnaire about what is going on at that time, what you are doing and how you are feeling. This shouldn't take any longer than 60-90 seconds to complete. If you are at school, we can schedule these notifications so that they do not go off when you are in class. We can also change the time that the notifications start in the morning and stop in the evening depending on when you usually wake up and go to sleep. You can select the day that you would like to start.

If you become distressed during the questionnaires or app data collection, you can stop completing that set of questions or stop with the study entirely. If this does happen, we would encourage you to speak with your CAMHS team, a trusted adult or access support from the helplines listed at the end of this information sheet. Please note that, to ensure your safety and wellbeing, if you score on a risk related measure the researcher will inform your CAMHS team.

As well as asking you questions about how you are feeling, what you are doing and what is happening around you, the app will also collect some broad data about how you interact with your mobile phone and about your activity levels. Data will be collected on how often and for how long you use certain apps on your phone, your activity levels (e.g. step count) and how much time you spend using your phone. This allows for us to look at the relationship between social media, mobile phones and activity levels and mental health and if this changes as lockdown restrictions change. The app you will download and use on your phone will only collect data on your physical activity level and data on how long the app is open. No content from the apps on your phone will be collected.

After the week of data collection, you will be given a debrief sheet. You can also opt in to have a meeting with the researcher where you can discuss your experiences and give any feedback that you have. You will also receive your £20 voucher at this point.

When the week is over, you can look at your data and share this with the clinician you are working with if you want to. This can be helpful in your sessions. When you are finished with the study you can delete the app from your phone.

You can choose to participate in follow-up data collection at the end of your treatment in CAMHS and after two years. You will be asked to complete the same set of questionnaires and data collection on the app. This allows us to see if and how things change over time. Participation in this is optional, you can let us know in the consent form if you would like to opt out of follow-up data collection. If you decide that you would like to participate in follow-up data collection, we would like to contact you at 6-month intervals to check if you are still being seen in CAMHS, whether you would still like to participate in follow up data collection and your contact details. We would ask that you or your clinician in CAMHS let the research team know when your treatment in CAMHS has come to an end so that we know follow-up data collection can begin.

What happens if the app stops working?

Don't worry if this happens. You can contact the researcher to let them know and they will help fix this.

What are the possible benefits?

You will have access to the questionnaire data on the app. You can share this with clinician if you choose to and you could use this information in sessions. This could allow you and your clinician to have a clearer understanding of your thoughts and feelings across the week and triggers for any changes in your mood.

By taking part in this study and sharing your experience with us, you will be helping the research team to better understand the factors that influence mental health

difficulties and positive treatment outcomes in CAMHS. Treatments can be developed and adapted based on this information.

You will be awarded a £20 shopping voucher as compensation for taking part in this study. You can let us know if you would like to receive this £20 voucher or not. You can still take part even if you do not want to receive the voucher. You can let us know within the online survey.

Are there any risks associated with taking part?

There are no major risks of taking part in this study. It will take a bit of time and some of the questions asked are related to your mental health. It is possible you find that distressing. If you do, you will be able to discuss this in sessions with the clinician you are seeing in CAMHS, or through the resources listed below if you are yet to be allocated a clinician.

Data protection and confidentiality

The NHS will manage your identifiable information (your “personal data”) as you are participating in a study conducted by a research team working at both NHS Lothian and the University of Edinburgh. We will ask for your consent to let your GP know that you are participating in this study.

We will keep your answers private. Your data will be referred by a unique participant number rather than by name. Your data will be only viewed by the research team. We won't put your name, address or school on the survey or anything else that would mean people would know it was you. We will also store digital data on secure password-protected computers within the University of Edinburgh. The app won't store any personal identifiable information or information about our study. The responses you give on the questionnaire will be stored securely by an external company (KU Leuven Research and Development based in Belgium). If your phone gets lost or stolen, you can get in touch with the research team who can ensure that any data on the app can be deleted remotely.

We will write up the results and publish them in an academic journal. If you would like to receive a summary of the results of the study once it is completed, please tick the appropriate box on the consent form. We will keep personal data for 12 months after the study has finished. We will store your anonymised data for 5 years after the study has been completed.

If you disclose any information that suggests that you or someone else is at risk of harm, we will share confidential information you provided with others (e.g. the Police, the parents, social services, or other teachers) and we may need to follow the school child protection guidance to ensure safety and wellbeing. These are situations where confidentiality would have to be breached, in order to ensure that you are able to obtain support if necessary, and to ensure your safety going forward. If this was necessary, we would always try to let you know first.

How will we use information about you?

We will need to use information from you for this research project.

This information will include your name and contact details (phone number and email address). People will use this information to do the research. If you consent to participating in follow-up data collection at the end of your treatment in CAMHS and after 2 years, we will ask you to provide your contact details and contact details of a trusted other and ask you to update us on any changes of contact details so that we don't lose touch with you.

If you consent to participating in follow-up data collection, researchers will have access to service level data on your medical records so that they know when you have been discharged from CAMHS. They will use this information to know when end of treatment data collection can be started.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. With your consent, your anonymised data will be uploaded to Edinburgh DataShare.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team and sending an email to the research team (contextualmh@ed.ac.uk)
- <https://www.ed.ac.uk/records-management/privacy-notice-research>

What will happen to the results of the study?

This study will be written up as theses for doctorates in Clinical Psychology and a publication that is submitted to a Peer Reviewed Journal. You will not be identifiable from any published results.

When we have finished this project, we would like to give other researchers the chance to use the anonymised data we have collected to answer their own questions. We wouldn't share any personal information about you with these researchers, like your name or your school, only questionnaire scores that people would not be able to tell was yours. You can tell us if you don't want us to share your answers with other researchers on the consent form.

If you would like to see a summary of this study's findings once the research has been completed, please tick the appropriate box on the consent form and this can be sent to you.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the East of Scotland Research Ethics Committee. NHS Management Approval has also been given.

Who can I speak to about the study?

If you have any questions about the study, you can ask the clinician that you are working with in CAMHS. You can also speak to the research team directly (email: contextualmh@ed.ac.uk) or you can speak to Connie or Sarah ().

If something goes wrong and you want to complain about this study, you can contact Angus Macbeth () who is the Director of Research and Knowledge Exchange, School of Health in Social Science at the University of Edinburgh.

Thank you for reading about our study!

If you would like to take part, please discuss this with your clinician in your next appointment at CAMHS or get in touch with the research team directly using the



contact details provided above.

Helplines support

If after completion of the survey you feel distressed or there are still things you may want to discuss your feelings and emotions, please contact the services listed below. They are confidential and free helplines open 24 hours and can assist you in an emergency or crisis.

Service	Phone Number	Opening Hours	What help does it provide?
NHS 24	111	When GP is not available	Clinical health and mental health support
Edinburgh Crisis Centre	080 801 0414	24 hours	Mental health support in an emergency or crisis
The Samaritans	116 123	24 hours	Mental health support in an emergency or crisis
Mental Health Assessment Service	0131 537 6000	24 hours	Mental health support in an emergency or crisis
ChildLine Scotland	0800 1111	Anytime	Mental health support in a crisis. Help if you need someone to talk to
Breathing Space	0800 83 85 87	6pm-2am Monday to Thursday, 6pm-6am Friday to Monday morning	Help if you are experiencing low mood or depression and need someone to talk to

STUDY INFORMATION

We would like to invite your child to take part in this research study. This sheet gives you some information about the study so that you can decide whether you are happy for your child to take part. If there is anything else that you would like to know, or if there is something that is not clear, please speak with the clinician who is working with your child in CAMHS, or you can contact the research team directly.

Why are we doing this study?

We are interested in looking at mental health in adolescents' daily lives and how they respond to stressors. We are interested in learning about the factors associated with the development and maintenance of mental health difficulties and what things change during treatment in CAMHS. We are also interested in looking at the impact of the covid-19 pandemic and the transition out of lockdown on young people's mental health and treatment. We would like to find out more about this by asking your child to complete some online questionnaires. We would also ask them take part in a week of data collection by downloading an app on their phone and completing short a short survey that takes around 60-90 seconds several times a day.

Who can take part?

Young people can take part if they are aged between 12-18 years old, are currently receiving treatment in CAMHS and are able and willing to take part. We will present this study to them and seek their written consent to participate.

Does my child have to take part?

No! It's completely up to you and your child. Choosing not to take part won't affect them in any way.

Can they change their mind?

Yes! Even if your child says yes now, they can decide to stop taking part at any time they want. They don't have to give a reason about why they want to stop if they don't

want to. You should note that your child's data may be used to produce formal research outputs such as journal articles, conference papers, theses, and reports prior to their withdrawal and so you or your child are advised to contact the research team at the earliest opportunity should you wish to withdraw your child from the study.

Deciding not to take part or withdrawing from the study will not affect your child's healthcare or treatment at CAMHS in any way.

What does this study involve?

In this study, your child will complete some online questionnaires and complete a 60-90 second survey on an app on their phone multiple times a day for a week. This helps us to get an understanding of their mental health and wellbeing in their everyday life.

If you decide that you are happy for your child to take part, you won't have to do anything. It's ok to opt your child out of this research. You can choose to opt them out now or change your mind later. If you would not like for your child to participate in this research, you can fill in the opt out form and they will be removed from the study. Even if your child has completed the consent form indicating that they would like to participate, if you decide you do not want them to, they will be opted out of the research.

If your child is interested in taking part, we have asked them to let their clinician in CAMHS know or contact the research team using the contact details at the end of this information sheet. We will then arrange a meeting with them to answer any questions you or your child may have about the study. We will ask them to sign a consent form to show that they want to participate in the research. It's ok for them to say no now or change their mind later.

We will then show them how to download and use an app on their phone. Here is a link to the app if you would like to read a bit more about it and see what it looks like: <https://m-path.io/landing/>. During this meeting they can practice using the app and ask any questions that they have.

During this meeting, they will be asked to fill out some online questionnaires on demographics, mental health and wellbeing at a time that suits them. Some of these

questions might be a bit hard to answer, but they are welcome to leave out any questions that they don't want to answer.

Your child will then complete the week of data collection using the app. If any problems arise during this time, you or your child can always get in touch with the researcher using the contact details given at the end of this information sheet.

We will ask them to carry the phone with them for a week. During that time a 'beep' notification will go off multiple times a day between 7am and 10.30pm (times can be personalised to your child) and they will be asked to fill in a short questionnaire about what is going on at that time, what they are doing and how they are feeling. This takes between 60-90 seconds to complete. We can schedule these alerts to go off after class if you are worried about it interfering with school. We can also change the time that the notifications start in the morning and stop in the evening depending on when they usually wake up and go to sleep. They can select the day that they would like to start.

Please note that, to ensure their safety and wellbeing, if they score on a risk related measure the researcher will inform your child's CAMHS team. Should they become distressed during the data collection, we have encouraged them to get in touch with their CAMHS team, speak with a trusted adult or access support from the helplines given at the end of their information sheet.

As well as asking questions about how they are feeling, what they are doing and what is happening around them, the app will also collect some broad data about how they interact with their mobile phone and about their activity levels. Data will be collected on how often and for how long they use certain apps on their phone, their activity levels (e.g. step count) and how much time they spend using their phone. This allows us to look at the relationship between social media, mobile phones and activity levels and mental health and if this changes as lockdown restrictions change. The app will only collect data on their physical activity level and how long apps are open for. No content from the apps on their phone will be collected.

After the week of data collection, they will be given a debrief sheet. They can also opt in to have a meeting with the researcher where they can discuss how they got on and give any feedback that they have. They will also receive a £20 shopping voucher at this meeting.

When the week is over, they can look at their data and share this with the clinician they are working with if they want to. This can be helpful in their sessions. When they are finished with the study, they can delete the app from their phone.

Your child can participate in follow up data collection at the end of their treatment in CAMHS and after two years. This allows us look at therapeutic progress and to see if and how things change over time. Participation in this is optional, they can let us know in the consent form if they would like to opt out of follow up data collection. If they decide that they would like to participate in follow up data collection, we would like to contact them at 6-month intervals to check if they are still being seen in CAMHS, whether they would still like to participate in follow up data collection and their contact details. We would ask that you, your child or their clinician in CAMHS to let the research team know when their treatment ends so that we know when follow up data collection can begin.

What happens if the app stops working?

Don't worry if this happens. You or your child can contact the researcher to let them know and they will help fix this.

What are the possible benefits?

Your child will have access to the questionnaire data on the app and they can use this therapeutically in sessions. They can share this with their clinician if they choose to and they could use this information in sessions. This could allow your child and their clinician to have a clearer understanding of their thoughts and feelings across the week and triggers for any changes in their mood.

By your child taking part in this study and sharing their experience with us, they will be helping the research team to better understand the factors that influence positive treatment outcomes in CAMHS. Treatments can be developed and adapted based on this information.

Your child will be awarded a £20 shopping voucher as compensation for participation in this study. Your child can let us know if they would like to receive this £20 voucher via the online consent form. Your child will still be able to take part in the study even if you do not wish for them to receive payment.

Are there any risks associated with taking part?

There are no significant risks associated with participation. During the data collection week, it will take a bit of your child's time. Some of the questions they are being asked are related to their mental health and it is possible that they might find these distressing. If they do, they will be able to follow the advice they have been given in CAMHS to manage difficult emotions, discuss this in the sessions they are having at CAMHS and use the resources signposted in the Information Sheet.

Data protection and confidentiality

We will keep your child's answers private. Your child's data will be referred to by a unique participant number rather than by name. Your child's data will be only viewed by the research team. We won't put your child's name, address or school on the survey or anything else that would mean people would know it was them. We will store digital data on secure password-protected computers within the University of Edinburgh. The app won't store any personal identifiable information or information about our study. The responses your child gives on the questionnaire will be stored securely by an external company (KU Leuven Research and Development based in Belgium). If your child's phone gets lost or stolen, you or your child can get in touch with the research team who can ensure that any data on the app can be deleted remotely.

We will write up the results and publish them in an academic journal. We will also share the results with your CAMHS team so you can see what we found out in the form of a generic report.

We will keep identifiable data for 12 months after the study has finished. We will store your child's anonymised data for 5 years after the study has been completed.

If your child discloses any information that suggests that they or someone else is at risk of harm, we will share this information with appropriate third parties (e.g. emergency services, child protection etc.). to ensure safety and wellbeing. Where possible, we will notify your child that we are going to do this first.

How will we use information about your child?

We will need to use information from your child for this research project.

This information will include their initials, name and contact details. People will use this information to do the research. If they consent to participating in follow up data collection at the end of their treatment in CAMHS and after 2 years, we will ask them to provide their contact details and contact details of a trusted other and ask them to update us on any changes of contact details so that we don't lose touch.

If you consent to your child participating in follow up data collection, researchers will have access to service level data on your child's medical records so that they know when your child has been discharged from CAMHS. They will use this information to know when end of treatment data collection can be started.

People who do not need to know who your child is will not be able to see your child's name or contact details. Your child's data will have a code number instead.

We will keep all information about your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are your choices about how your information is used?

- Your child can stop being part of the study at any time, without you or them giving a reason.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about your child.
- If your child agrees to take part in this study, you and your child will have the option for your child's anonymised data saved from this study being used in future ethically approved research. With their consent, your child's anonymised data will be uploaded to Edinburgh DataShare. Even if your child consents to this, you can opt your child out of this part of the study in the opt out form.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- At www.hra.nhs.uk/information-about-patients/
- By asking one of the research team via email: contextualmh@ed.ac.uk

- At <https://www.ed.ac.uk/records-management/privacy-notice-research>

What will happen to the results of the study?

This study will be written up for doctorate theses and for publication in a journal. Your child will not be identifiable from any published results.

When we have finished this project, we would like to give other researchers the chance to use the data we have collected to answer their own questions. We wouldn't share any personal information about your child with these researchers, like the name or the school, only questionnaire scores that people would not be able to tell was theirs. You can opt your child out of their data being shared with other researchers on the opt out form.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from the East of Scotland Research Ethics Committee. NHS Management Approval has also been given.

Who can I speak to about the study?

If you have any questions about the study, you can ask the clinician that you are working with in CAMHS to direct you to the research team. If you want to get in touch with the researchers directly you can speak to Connie or Sarah () or (). You can also contact the wider research team via email at: contextualmh@ed.ac.uk.

If something goes wrong and you want to complain about this study, you can contact Angus Macbeth () who is the Director of Research and Knowledge Exchange, School of Health in Social Science at the University of Edinburgh.

Thank you for reading about our study.

If you are happy for your child to take part, you do not need to do anything. If you would not like your child to take part in this research, please request a copy of and fill in the opt out form.



Helplines support

If after completion of the survey you feel distressed or there are still things you may want to discuss your feelings and emotions, please contact the services listed below.

They are confidential and free helplines open 24 hours and can assist you in an emergency or crisis.

Service	Phone Number	Opening Hours	What help does it provide?
NHS 24	111	When GP is not available	Clinical health and mental health support
Edinburgh Crisis Centre	080 801 0414	24 hours	Mental health support in an emergency or crisis
The Samaritans	116 123	24 hours	Mental health support in an emergency or crisis
Mental Health Assessment Service	0131 537 6000	24 hours	Mental health support in an emergency or crisis
ChildLine Scotland	0800 1111	Anytime	Mental health support in a crisis. Help if you need someone to talk to
Breathing Space	0800 83 85 87	6pm-2am Monday to Thursday, 6pm- 6am Friday to Monday morning	Help if you are experiencing low mood or depression and need someone to talk to

Appendix 9 – 12-18 Consent Form

CAMHS CONSENT FORM**(Paper Format)**

Please only fill in this form once you have read the information sheet and asked any questions that you have about the study.

Your name: _____

Your age: _____

Today's date: _____

Please write your initials in each box if you agree:

I have read the information sheet for the above study (version 6, 08.06.2023)	
I understand the information the researchers provided about this study and have been able to ask any questions I had about the study and have had them answered satisfactorily.	
I understand that my participation is voluntary and that I can ask to stop at any time without having to give a reason and without my medical care being affected.	
I understand that my anonymised data will be stored for a minimum of 5 years.	
I understand that I will download an app on my phone for this study and this app will collect data on my screen time, how often and for how long I use certain apps as well	

as information about my activity levels (e.g. step count). No content from any of the apps will be collected.	
I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor(s) (NHS Lothian and the University of Edinburgh) or from the/other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records	
I understand that the app will not store any personal identifiable information or any information about the study. I understand that the responses I give will be stored securely by an external company (KU Leuven Research and Development based in Belgium)	

The following statement is optional. You can still take part in the study if you do not consent to these parts. Please give your initials in each box if you agree.

I agree that my GP will be informed of my participation in the study (optional)	
I agree for my anonymous answers to go into the anonymous dataset that gets shared with other researchers to be used in future research (optional)	
I agree to be contacted to take part in follow up data collection and be contacted by the research every 6 months until the end of the study (optional)	
If so, I agree for researchers to access service level information (e.g. if you are being seen in CAMHS, not the content of sessions) on my electronic health records so that they know when my treatment in CAMHS has come to an end (optional)	
I agree to be contacted to take part in follow up data collection two years later (optional)	
I would like to see a summary of this study's findings once the research has been completed (optional)	

****Please only read this section if you are aged 12-15 years****

Does your parent not want you to take part in certain parts of this study or this study as a whole?

- If your parent is **happy for you to participate** in this study, please hand in this consent form to the researcher.
- If your parent **does not want you to take part in certain parts of this study or this study as a whole**, please **click on the box below**.

Your caregivers DO NOT want you to take part of this study or some parts of it, please select an option below:

My caregiver DOES NOT want me to take part in the study as a whole	
My caregiver DOES NOT want me to take part in study part 1 (questionnaires)	
My caregiver DOES NOT want me to take part in study part 2 (m-path)	
The following statement is optional. You can still part in the study if your caregiver does not consent to these.	
My caregiver DOES NOT want my anonymous answers to go into the anonymous dataset which gets shared with other researchers to be used in the future	

Appendix 10 – Debrief Form



Debriefing

Thank you for taking part in this study!

What do we want to know?

We know that adolescence (teenage years) can be an exciting but difficult time in a person's life. Mental health problems are more common during this time, likely due to many stressors such as exams, change in relationships, peer pressure, changes in the body and brain and thinking about the future. This time can be even harder for those who have experienced trauma. Whilst many studies have looked at the important factors involved in adolescents' mental health, such as supportive relationships, at one time point, not many studies have looked at these factors in daily life. By taking part in this study, you have helped the researchers to understand how different things affect adolescents' mental health in real life settings, over time. We hope that we can share this information with others, such as mental health services, to improve mental health for adolescents.

What will you do with my answers?

We want to remind you that the data you have provided has been protected and is only accessible by the research team. We have created steps to keep this data confidential, such as by using a unique identifier number. We will delete any identifiable information once the study is completed. Data will be anonymous in writing up the study for academic publications, reports, and conferences presentations. Your personal information and individual data will not be available to anyone outside research team and will not be passed to anyone else.

What if I want to withdraw from the study?

You can withdraw from the study at any time. If you do not want your data to be used in the write up of the study, you would need to let us know before this happens and if possible, at the earliest opportunity. You can do this by contacting one of the research team; the contact details are provided on this sheet. We will use your unique identifying number to identify which data is yours, and then destroy it.

What if I do not feel well after participating in this study or want to speak to someone about it?

If taking part in this study has raised any specific concerns about your mental health and well-being, then please speak to an adult that you trust. This could be someone at home, a family member, or an adult in school. If you want to speak to someone in private, you can speak to an adult at Childline by calling 0800 1111 or visiting <https://www.childline.org.uk/get-support/> or at the NSPCC by calling 0800 1111 or visiting: <https://www.nspcc.org.uk/preventing-abuse/our-services/childline/>. You may want to have a look also at the flyer in attachment for more advice and options.

Any other questions?

If you have any comments or questions about this study, please, contact:	Sarah Gilchrist Clinical Psychology, School of Health in Social Science Doorway 6, Medical School, University of Edinburgh, EH8 9AG Connie McKeand Clinical Psychology, School of Health in Social Science Doorway 6, Medical School, University of Edinburgh, EH8 9AG
If you have any further questions related to this study, that you would like to discuss with an independent contact person, please get in touch with:	Dr David Gillanders 0131 651 3946; 07813 929 901 Email: Head of Clinical & Health Psychology University of Edinburgh School of Health in Social Science Teviot Place Edinburgh EH8 9AG
If you have any complaints about this study, please, contact:	Dr Tim Bird Email: Head of School for Health in Social Science University of Edinburgh School of Health in Social Science Teviot Place Edinburgh EH8 9AG

Where can you get help and support?

Sometimes you can cope with problems on your own and get over them. Other times, you may need some extra help.

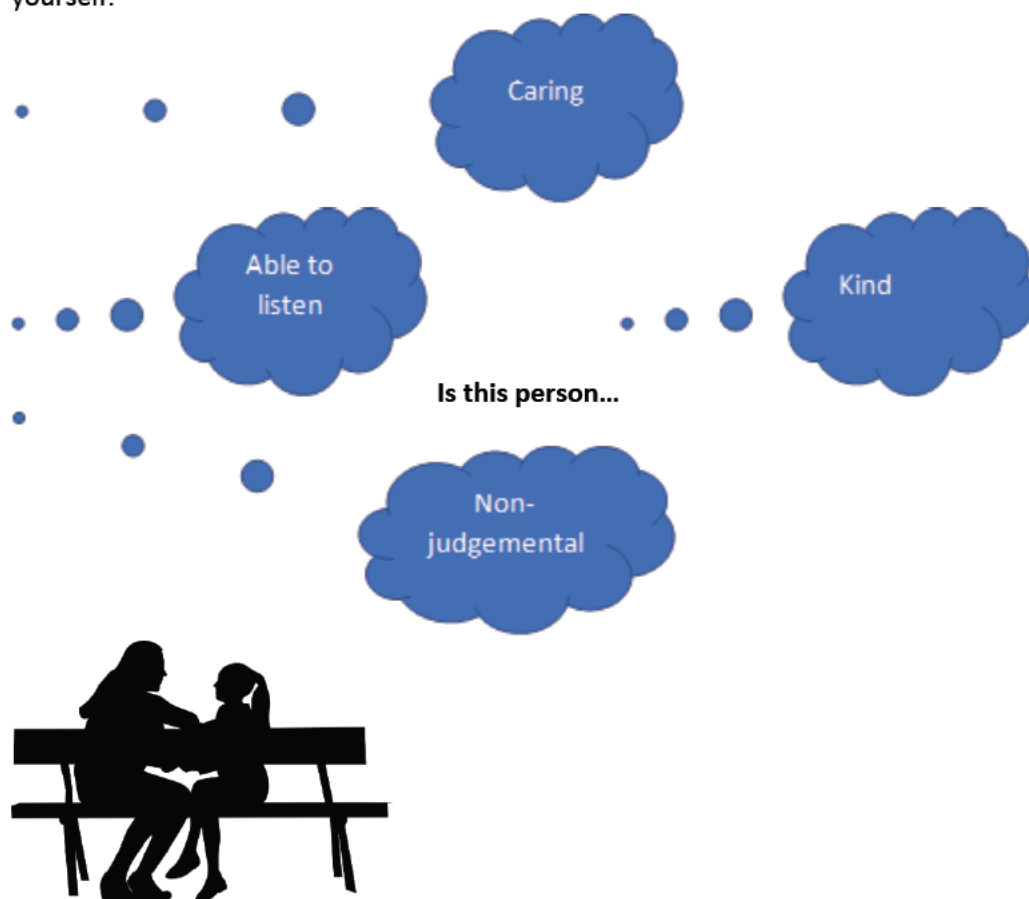
Everyone has mental health, and this affects all aspects of our life. Like physical health, mental health is important.

It is okay to talk about your feelings, thoughts, and emotions.

If you wish to talk more about what is going on in your head, you may try the following steps:

1) Find a trusted adult you know you can talk to. How do you find one?

Think about the people around you, a teacher you know at school or any of your relatives, and ask yourself:



2) Prepare yourself for what you want to talk about. You might find it helpful to write some things down. Agree with that person on a time to talk and find a private and quiet space.

3) Take a deep breath and talk...! Reaching out for help can be hard but the person you have picked

Sometimes, talking to a trusted adult may not be enough and some more help is needed by professionals. Here are some services that can help you that are free to call, provide anonymous advice, and you can reach them any time:

Service	Phone Number	Opening Hours	What help does it provide?
NHS 24	111	Mental health hub is open 24/7	Clinical physical health and mental health support
Edinburgh Crisis Centre	080 801 0414	24 hours	Mental health support in an emergency or crisis
The Samaritans	116 123	24 hours	Mental health support in an emergency or crisis
Mental Health Assessment Service	0131 537 6000	24 hours	Mental health support in an emergency or crisis
ChildLine Scotland	0800 1111	24 hours	Mental health support in a crisis. Help if you need someone to talk to
Breathing Space	0800 83 85 87	6pm-2am Monday to Thursday, 6pm-6am Friday to Monday morning	Help if you are experiencing low mood or depression and need someone to talk to

Appendix 11 – Journal Author Guidelines

AUTHOR GUIDELINES

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Submission
 Aims and Scope
 Manuscript Categories and Requirements
 Preparing the Submission
 Editorial Policies and Ethical Considerations
 Author Licensing
 Publication Process After Acceptance
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 Editorial Office Contact Details

1. SUBMISSION

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The *British Journal of Clinical Psychology* publishes original research, both empirical and theoretical, on all aspects of clinical psychology:

clinical and abnormal psychology featuring descriptive or experimental studies
 aetiology, assessment, and treatment of the whole range of psychological disorders
 irrespective of age group and setting
 biological influences on individual behaviour

studies of psychological interventions and treatment on individuals, dyads, families, and groups

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The Journal is catholic with respect to the range of theories and methods used to answer substantive scientific problems. Studies of samples with no current psychological disorder will only be considered if they have a direct bearing on clinical theory or practice.

The following types of paper are invited:

papers reporting original empirical investigations;

theoretical papers, provided that these are sufficiently related to empirical data;

review articles, which need not be exhaustive, but which should give an interpretation of the state of research in a given field and, where appropriate, identify its clinical implications;

Brief Reports and Comments.

3. MANUSCRIPT CATEGORIES AND REQUIREMENTS

Papers describing quantitative research should be no more than 5000 words (excluding the abstract, reference list, tables, and figures). Papers describing qualitative research (including reviews with qualitative analyses) should be no more than 6000 words (including quotes, whether in the text or in tables, but excluding the abstract, tables, figures and references).

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In exceptional cases the Editor retains discretion to publish papers beyond this length where the clear and concise expression of the scientific content requires greater length (e.g., explanation of a new theory or a substantially new method). Authors must contact the Editor prior to submission in such a case.

Refer to the separate guidelines for [Registered Reports](#).

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Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision. The title page of the manuscript, including a data availability statement and your co-author details with affiliations. (*Why is this important? We need to keep all co-authors informed of the outcome of the peer review process.*) You may like to use [this template](#) for your title page.

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Keywords

Data availability statement (see [Data Sharing and Data Accessibility Policy](#));

Acknowledgments.

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Provide appropriate keywords.

Acknowledgments

Contributions from anyone who does not meet the criteria for authorship should be listed, with permission from the contributor, in an Acknowledgments section. Financial and material support should also be mentioned. Thanks to anonymous reviewers are not appropriate.

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For help with submissions, please contact: Hannah Wakley, Associate Managing Editor (bjc@wiley.com) or phone +44 (0) 116 252 9504.

Appendix 12- Protocol

Non-CTIMP Study Protocol

Investigating psychological predictors of stress and mechanisms of change in mental health treatment in adolescents

	The University of Edinburgh and Lothian Health Board ACCORD The Queen's Medical Research Institute 47 Little France Crescent Edinburgh EH16 4TJ
Protocol authors	Emma Martin, Jordan Anthony Bibby, Matthias Schwannauer, Sarah Gilchrist, Connie McKeand, Islay Barne, Koraima Sotomayor-Enriquez, Simona Di Folco
Chief Investigator	Professor Matthias Schwannauer
Sponsor number	CAHSS2012/07
REC Number	21/ES/0043
Version Number and Date	Version 5, 27/06/2023

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LIST OF ABBREVIATIONS

ACCORD	Academic and Clinical Central Office for Research & Development - Joint office for The University of Edinburgh and Lothian Health Board
CAMHS	Child and Adolescent Mental Health Service
CI	Chief Investigator
CRF	Case Report Form
ESM	Experience Sampling Method
GCP	Good Clinical Practice
ICH	International Conference on Harmonisation
PI	Principle Investigator
QA	Quality Assurance
REC	Research Ethics Committee
SOP	Standard Operating Procedure

1 INTRODUCTION

1.1 BACKGROUND

Adolescence is a critical time for the emergence of mental health problems. The World Health Organisation estimates that 50% of all mental health problems occur by the age of 14 and 75% occur by the age of 18 (ICD-10, 2004). To understand how to tackle these difficulties effectively, a greater understanding of the factors that influence the development and maintenance of these problems in adolescence is needed. It is also vital to understand how and why established treatments work in this age group.

Mentalization, the awareness that we have of our own and other people's thoughts and feelings and the ability to use this information to understand other people's behaviour, is something that most people are able to do intuitively. Difficulty with mentalizing is a transdiagnostic factor implicated in the development and maintenance of mental health (MH) difficulties (Bateman and Fonagy, 2004). Research also suggests that coping is another transdiagnostic factor associated with mental health difficulties (Horwitz, Hill and King, 2011). Both of these factors are understood to originate within attachment relationships, early in development and beyond (Bateman & Fonagy, 2004). Adolescents who are struggling with their mental health are seen by CAMHS and may be offered psychological therapy, medication or another type of therapy. We are interested in exploring is how the

transdiagnostic factors most sensitive to psychological treatment, mentalization, attachment and coping, relate to how adolescents with mental health difficulties response to stress in their everyday lives, whether reflective functioning and coping develops over the course of their treatment and whether this is associated with reduced everyday stress.

1.2 RATIONALE FOR STUDY

Adolescence is a critical time for the development and treatment of mental health difficulties, with half of all mental health problems emerging by the age of 14 and 75% by the age of 24 (Kessler et al., 2007). As such, early intervention is one of the key recommendations from the Children and Young People's Mental Health Task Force and has been identified by a priority by the Scottish Government in the Mental Health Strategy 2017-27 .

Research suggests that coping, attachment and mentalization are transdiagnostic factors associated with the development and maintenance of mental health difficulties (Luyten et al., 2020; Andro, 2012). There has been limited research into how mentalization, attachment and coping are associated with adolescents with mental health difficulties response to everyday stressors. We are interested in exploring is how the transdiagnostic factors most sensitive to psychological treatment, mentalization, attachment behaviours and coping, relate to how adolescents with mental health difficulties response to stress in their everyday lives, whether reflective functioning and coping develops over the course of their treatment and whether this is associated with reduced everyday stress. No studies so far have focused on whether there are significant improvements in these factors as a result of treatment in CAMHS and how this varies across the type of input the young person receives. A greater understanding of these questions would further our knowledge and understanding of factors influencing the maintenance of mental health difficulties and what factors influence positive treatment outcomes in both the short and longer term. This would allow for current approaches to treatment to be optimised and holds the possibility of new treatments being developed.

Attachment theory is a comprehensive framework of social and emotional development across the lifespan (Bowlby, 1969, 1973, 1980, 1982) and attachment is understood to be the foundation of mentalization ability (Bateman & Fonagy, 2004). Subsequently, this theory permeates through many psychological models of, and treatments for, mental ill-health. One fundamental premise of attachment theory is that security or insecurity in early key relationships leads to corresponding stable patterns of attachment behaviours throughout life. In turn, these patterns of behaviour shape the experience of the self and others (Gorrese & Rugierri, 2013), cognitive appraisals of threat (Ein-Dor et al., 2011), emotions and affect regulation (Pascuzzo et al., 2015; Brumariu, 2015), physiological response to stress (Kidd et al., 2011) and outcomes of psychological therapy (Taylor et al; 2015; Degnan et al., 2016). However, findings in attachment research come under scrutiny due to methodological limitations in how attachment behaviours have been measured (Ravitz et al., 2010). Another fundamental, but largely ignored, premise of attachment theory, is that it is a 'person-by-situation' interactionist framework (Cook, 2000; Campbell & Marshall, 2011; Simpson & Winterheld, 2012). Despite this, patterns of attachment behaviour have primarily been measured at static time points via self-report methods or in laboratory settings with poor applicability to real-life situations. Advances in technology and methodology, such as with experience sampling methodology (ESM), means there can be valid investigation of attachment theory hypotheses, moment-by-moment and in real-life settings.

This study will focus on adolescent mental health, coping and distress. These topics are highly relevant in the current context of the covid-19 pandemic. The pandemic and associated lockdown has resulted in significant and unprecedented changes to our everyday lives. Numerous stressors have arisen as a result of this including school closures, isolation, economic instability, bereavements and ill health. There are high levels of uncertainty and research has suggested that young people have a range of covid-19 related worries. Many go-to coping strategies are not possible due to current restrictions. Furthermore, factors such as phone usage, social media usage and activity levels that are known to be associated with mental health will likely have been affected by lockdown. This study is therefore ideally placed to examine the impact of the covid-19 pandemic and the transition out of lockdown on adolescents mental health and the factors influencing resilience. It is likely that as a result of these stressors demand for mental health support is therefore likely to increase. As a result of the pandemic the delivery of mental health care has had to adapt- with some services halting treatment and others replacing face-to-face appointments with video and telephone contact. This study will also examine the impact of the covid-19 pandemic and the transition out of lockdown on adolescents' mental health, factors related to emotional wellbeing and treatment outcomes.

This study will look at adolescents who are receiving treatment in CAMHS and take measures of everyday distress, mentalization and coping. Whilst constructs such as mentalization and coping can be measured through cross sectional questionnaires, using an Experience Sampling Method (ESM) to measure everyday affect and distress has greater validity (Myin-Germeys et al., 2018). ESM utilises a structured diary technique as a means of collecting data from human participants in their everyday lives. This approach allows for researchers to get a greater understanding of how an individual's experience and behaviour interacts with their real life environment. This approach contrasts with standard questionnaires that rely on retrospective recall and minimises the effect of recall bias. This study will use a combination of cross sectional questionnaires and ESM.

2 STUDY OBJECTIVES

2.1 OBJECTIVES

2.1.1 Primary Objective

To examine if transdiagnostic factors, mentalization and coping, are associated with adolescents attending CAMHS' response to everyday stressors

To examine if there are patterns of attachment behaviour and the use of certain coping styles associated with levels of everyday distress and mental health difficulties in adolescents attending CAMHS

To examine if treatment in CAMHS is associated with a change in adolescents' mentalization, attachment behaviours and coping and if these changes are associated with reduced levels of everyday distress

To examine the impact of the covid-19 pandemic and the transition out of lockdown on adolescents' mental health and CAMHS treatment

3 STUDY DESIGN

A longitudinal cohort design will be used.

Following ethical approval, information about the study and recruitment will be provided to clinicians in CAMHS teams in the NHS Lothian Health Board. Any young person identified as being eligible for the study by the clinician they are working with will receive an information pack with a detailed description of the study to review. If the child is under aged 15 or under, their parent/ caregiver will also have access to an information pack and consent form with the option of opting their child out of the research. Participants will be informed that their consent to participate in this study is on a voluntary basis and they can choose to withdraw from the research at any time with no explanation required. Participants and their caregivers will be informed that patient identifiable information will be stored securely on NHS servers and data collected on the app will be anonymised and stored separately and securely on the University of Edinburgh server, with only trained researchers having access to this.

Adolescents and their caregivers will have a phone call with the researcher and will have the opportunity to ask any questions about the study when deciding if they want to participate. Consent will be sought and then researcher will help the young person to set the app up, practice completing questions and answer any questions. Contact details for the participant and a trusted other will be sought at this stage. The participant will be asked to update the research team of any changes to this during their participation in the study. The young person will be reminded that if they are participating in follow up data collection, the research team will get in touch every six months to check on their treatment status, their contact details and whether they would like to continue with the study.

The young person will then complete a series of online cross-sectional questionnaires related to mental health, mentalization and coping. To complete the ESM data collection, the young person will be asked to download an app on their mobile phone. The app will send notifications to prompt them to complete a brief questionnaire 10 times a day for seven consecutive days. On the app they will answer questions on positive and negative affect items, social context items and social context appraisals. The ESM app will also gather superficial data about factors related to mental health, specifically phone usage, social media usage activity levels and activity levels. This means that data can be gathered about social media app usage (e.g. which apps are open and for how long), activity levels (e.g. step count) and screen time (e.g. how long is phone unlocked for). This allows for a greater understanding of how the use of social media, mobile phones and activity levels change as lockdown restrictions change and how this is associated with mental health. It is not possible for data about the content of apps to be collected. During the week of data collection, participants can get in touch with the researcher if any problems arise. At the end of the week, participants will be given a debrief sheet and can opt in to have a debrief call with

the researcher to discuss their experiences, ask any questions they have and give feedback. This feedback will be used by the research team to develop and adapting the study. Data from this part of the study will be collected, analysed and the results will be written up in relation to the first study objective. Adolescents who have consented to follow up will be contacted to every six months to check whether they are still being seen by CAMHS, whether they want to continue with the study and confirm contact details. At the end of their treatment in CAMHS, either the participant or the clinician will contact the research team to let them know that follow up data collection can begin. After two years the research team will contact the participant to ask if they would like to participate in the last set of data collection. During follow up, adolescents will complete the same set of questionnaires and ESM data collection. They will receive the same contact with the researchers. Data from the whole study will be collected and analysed and the results of this will be written up.

4 STUDY POPULATION

4.1 NUMBER OF PARTICIPANTS

Participants will be adolescents aged between 12-18 who are receiving treatment in CAMHS. Participants will be recruited from the outpatient CAMHS teams in NHS Lothian. Recruitment will commence once ethical approval from the NHS has been obtained. 60 participants will be recruited. At the start of the study, they will complete questionnaires and then a week of ESM data collection. This will be repeated at the end of their treatment in CAMHS and again after two years if they have consented to participate in follow up.

4.2 INCLUSION CRITERIA

Participants will be included in the study if:

They are receiving treatment in CAMHS

They are aged between 12-18 years old.

They are willing to take part and are able to understand the information sheet about the study

5 PARTICIPANT SELECTION AND ENROLMENT

5.1 IDENTIFYING PARTICIPANTS

Information about the study and recruitment will be provided to appropriate clinicians in CAMHS teams in the NHS Lothian Health Board. Potential participants will initially be approached by a clinician in their direct clinical care team if that clinician believes they might be eligible for the study and meets the inclusion criteria. Clinicians will be able to discuss the study in their routine sessions with potential participants and provide them with information sheets. If the young person identifies an interest in participating, they will have a call with the researcher to discuss this further and answer any questions.

5.2 CONSENTING PARTICIPANTS

Potential participants will be provided with developmentally appropriate information sheets. They will have time to read over this in between their routine sessions (typically 1-2 weeks) and have the opportunity to the researchers any questions that they have about the study. Participants aged between 12-15 will be asked to show their parents an information sheet and opt out form. Participants aged between 16-18 will be deemed able to consent to participating in the research as they will have consented to treatment in CAMHS.

Participants will be offered the opportunity to receive a £5 shopping voucher for participation in the study. Due to the burden and response rate required by participants, 53% of experience sampling methodology studies have reported employment of quasi-monetary incentive methods (Gabriel et al., 2019; whilst a third of studies identified by this review did not report which incentives were used). These studies have also rewarded participants on rate of completion, to increase responses and create fairness in rewards (Bono et al., 2013; Heller

& Watson, 2005; Butts et al., 2015; Liu et al., 2017; Matta et al., 2017). The number of monetary prizes and draws has varied between ESM studies. The voucher payment is consistent with the British Psychological Society Code of Human Research Ethics (Oates et al., 2021; Pg. 19-20), stating that payment should be offered to participants whereby they are giving a substantial amount of time. This payment is suggested to be small enough as to not compromise freely made decisions, be given across all participants, and as such is matched to the minimum wage for those under 18 years of age. Existing participants will be contacted via the contact details they provided (telephone or email) to inform them that they may be awarded the £5 voucher and will be asked if they would like to receive this. This choice will be recorded on the file which includes the pseudonymised participant ID numbers and saved on an NHS Lothian server. E.g., next to the participant 'JB003', it will be recorded as 'consented to receive voucher' or 'did not consent to receive voucher'. For new participants, there will be a section within the online survey, where participants can consent to receive the voucher or not. They will still be able to participate if they opt-out of this and will be informed of this. This will be recorded on the same file as their pseudonymised ID number, saved on an NHS Lothian server.

5.2.1 Withdrawal of Study Participants

Participants are free to withdraw from the study at any point or a participant can be withdrawn by the Investigator. If withdrawal occurs, the primary reason for withdrawal will be documented in the participant's case report form, if possible. The participant will have the option of withdrawal from:

- (i) all aspects of the trial

A participant who no longer wants to continue with the study can choose to do so at any time and they will not have to provide any reasons why they have made this decision. They will however be made aware that feedback is appreciated if they feel able to do so. If they wish to do so during the questionnaires or ESM data collection, they can simply stop where they are. They can let their clinician know that they have chosen to withdraw from the study in their next appointment and they can delete the app from their phone as soon as they wish.

6 STUDY ASSESSMENTS

6.1 STUDY ASSESSMENTS

[illegible]

Participants will be invited to look through information sheets, complete consent forms and fill out questionnaires on Qualtrics. Participants will be assigned anonymous personal identifiers to guarantee confidentiality and prevent names being linked to individual data. Personal identifiers will be stored securely on an NHS server.

Daily life data will be collected with the ESM, using an ‘app’ called MPath. The responses given on the app will be stored securely by an external company (KU Leuven Research and Development based in Belgium)

Data gathered from the app will be anonymised, transferred and stored on DataStore (<http://www.eeo.ed.ac.uk/it/DataStore.html>), a storage space in the University of Edinburgh server. Only researchers who are associated with the study and who have received Mantra training will have access through DataSync (<https://www.ed.ac.uk/information-services/computing/desktop-personal/datasync>) a Dropbox like hosting service for data sharing with controlled access, approved by the University of Edinburgh.

Anonymised data will be stored for 5 years. With participants consent, anonymised data will be uploaded to Edinburgh Data Share for ongoing use by the wider research community

7 DATA COLLECTION

In the first step of data collection, participants will be invited to fill out questionnaires on Qualtrics. In the next stage, daily life data will be collected on this app that will either be downloaded on the participants phone. The app will prompt participants no more than 10 times per day for seven consecutive days to complete a brief questionnaire. The questionnaires will take no between 60-90 seconds to complete and the content will consist of positive and negative affect items, their thoughts and feelings, current activities and event related context. These items are largely based on the questions from a study running in Belgium and Germany. These prompts can occur outwith class times at school to reduce disruption and distractibility. The sampling will take place between 7-10.30 pm, unless the participant reports different times for going to sleep and waking up. The ESM app will also gather superficial data about factors related to mental health, specifically phone usage, social media usage activity levels and activity levels. This means that data can be gathered about social media app usage (e.g. which apps are open and for how long), activity levels (e.g. step count) and screen time (e.g. how long is phone unlocked for). It is not possible for data about the content of apps to be collected. This allows for a greater understanding of how the use of social media, mobile phones and activity levels change as lockdown restrictions change and how this is associated with mental health. During the week of data collection, the young person can contact the research team if any issues arise. After the week of ESM data collection, the young person will receive a debrief sheet and can opt in to a debrief call. They can share their data with their clinician in CAMHS if they choose to and can delete the app from their phone.

If the young person has consented to participating in follow up data collection, the participant or the clinician will be asked to let the researchers know when their treatment has come to an end in CAMHS. Once this has occurred, they will be contacted and follow up data collection will begin. They will complete the same set of questionnaires and ESM data collection. This procedure will be repeated after two years.

7.1 Source Data Documentation

Mentalization: The Reflective Functioning Questionnaire (RFQ) (Fonagy et al., 2016)

The Reflective Functioning Questionnaire is a self-report measure. This questionnaire uses a 7 point Likert scale and answers range from strongly disagree to strongly agree. The RFQ includes two subscales on

certainty and uncertainty about mental states. The certainty subscale allows for the measurement of hypermentalizing and asks participants to rate how much they disagree with statements such as “people’s thoughts are a mystery to me”. On the uncertainty subscale participants are asked to rate how much they agree with statements such as “sometimes I do things without really knowing why”. Higher scores on this scale are indicative of hypomentalizing. The RFQ has been found to have acceptable internal consistency (Clinical sample: uncertainty subscale $\alpha=.77$ and certainty subscale $\alpha=.65$; Non-Clinical sample: uncertainty subscale $\alpha=.77$ and certainty subscale $\alpha=.67$). It also demonstrated excellent test-retest reliability over a three week period ($r_s=0.84$ for the uncertainty subscale, $r_s=0.74$ for the certainty subscale) (Fonagy et al., 2016)

Coping: The Cognitive Emotion Regulation Questionnaire (CERQ) (Garnefski & Jraajj, 2006)

The Cognitive Emotion Regulation Questionnaire is a self-administered questionnaire that will be used to identify the cognitive coping strategies someone utilises following an aversive or challenging event. This questionnaire consists of 9 subscales: Self-blame, Other-blame, Rumination, Catastrophising, Putting into Perspective, Positive Refocusing, Positive Reappraisal, Acceptance and Planning. This questionnaire uses a 5 point Likert scale with answers ranging from almost never to almost always. A higher score is reflective of the more a coping is used. The short version demonstrates an acceptable level of reliability (Self-Blame $\alpha=.68$, Acceptance $\alpha=.73$, Rumination $\alpha=.79$, Positive Refocusing $\alpha=.80$, Refocus on planning $\alpha=.79$, Positive reappraisal $\alpha=.81$, Putting into Perspective $\alpha=.79$, Catastrophising $\alpha=.81$ and Other-Blame $\alpha=.77$) (Garnefski & Jraajj, 2006).

Mental Health: Mood and Feeling Questionnaire (MFQ) (Angold et al., 1995)

The Mood and Feeling Questionnaire will be used to provide a measure of depression. This questionnaire has been found to be a reliable and valid measure in both clinical and non-clinical samples (Burelson Daviss et al., 2006). The short version of the MFQ has been selected to reduce participant burden. This takes approximately 3-5 minutes to complete and has been found to strongly correlate with the longer version of the questionnaire (Thabrew et al., 2018) This questionnaire has 13 items and participants respond with either ‘not true’= 0 points, ‘sometimes true’= 1 point or ‘true’= 2 points. Higher scores on this questionnaire indicate more severe depressive symptoms.

Paranoia: The Paranoia Worries Questionnaire (Freeman et al., 2020)- This is a five-item questionnaire assessing the degree to which an individual has been worrying in the past month about others trying to harm them. Each item is rated on a 0 (none of the time) to 4 (all of the time) scale. Higher scores indicate higher levels of worry with paranoia content.

Perceived Loneliness: UCLA Loneliness Scale (Russell et al., 1978)- This is a 20-item scale designed to measure one’s perceived feelings of loneliness as well as feelings of social isolation. Participants rate each item as either O (“I often feel this way”), S (“I sometimes feel this way”), R (“I rarely feel this way”), N (“I never feel this way”).

Wellbeing: Warwick-Edinburgh Mental Wellbeing Scale (WEMWBS, Tennat et al., 2007)- The WEMWBS is a 14-item scale; each answered on a 1 to 5 Likert scale, ranging from “none of the time” to “all the time”. Items cover different aspects of well-being and are worded positively such as “I’ve been feeling relaxed”, and “I’ve been dealing with problems well”. An overall score is calculated by summing the scores for each item, with the minimum overall score being 14 and maximum score being 70. A higher score indicates a higher level of SWB.

Perceived Social Support: Multidimensional Scale of Perceived Social Support (MSPSS; Zimet et al., 1988)- is a 12-item measure of perceived adequacy of social support from three sources: family, friends, and significant other using a 5-point Likert scale (0 = strongly disagree, 5 = strongly agree).

Experiential Avoidance: The Brief Experiential Avoidance Questionnaire (BEAQ; Gamez et al., 2014)- comprises 15 items and is a measure of avoidance of sensations, experiences, and emotions, rated on a 6-point scale ranging from 1 (strongly disagree) to 6 (strongly agree).

Experience Sampling Method

Semi- random time contingent ESM will allow for assessing moment to moment variation in the real world and real time with high ecological validity. The specific ESM items will largely be based on the questions of a study already running in Belgium and will mirror the concepts in the baseline measures described above. The items will be designed to not be time consuming and questions will focus on the how the individual is responding in that moment, as opposed to focusing on their experiences in general. Visual analogue scales will be used as the measurement instrument. Previous research has demonstrated the feasibility, reliability and validity of the assessment method (Csikszentmihaly & Larson, 2014; Santangelo et al., 2013).

8 DATA MANAGEMENT

8.1.1 Personal Data

The following personal data will be collected as part of the research: demographic data on age, gender and socio-economic status. Participants will sign an online consent form.

Data Information Flow

Personal data will be collected throughout the study and will be destroyed within 12 months of completion of the study.

8.1.2 Transfer of Data

Data collected or generated by the study (including personal data) will not be transferred to any external individuals or organisations outside of the Sponsoring organisation(s).

8.1.3 Data Controller

A data controller is an organisation that determines the purposes for which, and the manner in which, any personal data are processed.

The University of Edinburgh and NHS Lothian are joint data controllers along with any other entities involved in delivering the study that may be a data controller in accordance with applicable laws (e.g. the site)

8.1.4 Data Breaches

Any data breaches will be reported to the University of Edinburgh and NHS Lothian Data Protection Officers who will onward report to the relevant authority according to the appropriate timelines if required.

9 STATISTICS AND DATA ANALYSIS

9.1 SAMPLE SIZE CALCULATION

The sample size for this study is 60. In ESM research, a high number of data points is achieved from each individual because participants respond multiple times a day over numerous day. As such, a small sample size of participants is sufficient in statistical analyses that model within person relationships. A sample size of 60 will initially be recruited for to account for the possibility of attrition over the course of the study.

9.2 PROPOSED ANALYSES

Prior to analysis the data will be cleaned and checked.

ESM data collection involves a large number of repeated measurements on multiple variables per participant, meaning that data includes multiple responses nested within an individual. ESM data have a complex structure and the assumptions of traditional statistical methods such as a repeated measures ANOVA are not met.

Multilevel modelling is a more appropriate method of analysis for ESM data (Gabriel et al., 2019). As such, multilevel models will be used to analyse the ESM data gathered in this study.

10 RISKS

As the participants will be receiving support from CAMHS for their mental health, it is possible that over the course of the data collection period they may experience distress. They will be encouraged to follow the strategies they are learning in CAMHS if that is manageable, to contact their local CAMHS team's duty service or to get in touch with emergency services if necessary. If the young person's response on the experience sampling questions or questionnaires are relevant for risk related measures, the research team will make the young person's key worker in CAMHS aware of this. Changes in distress linked to participation in the study will also be measured and if distress seems to be linked with involvement in the study, the researcher and young person will discuss any further engagement in the study.

11 OVERSIGHT ARRANGEMENTS

11.1 INSPECTION OF RECORDS

Investigators and institutions involved in the study will permit trial related monitoring and audits on behalf of the sponsor, REC review, and regulatory inspection(s). In the event of audit or monitoring, the Investigator agrees to allow the representatives of the sponsor direct access to all study records and source documentation. In the event of regulatory inspection, the Investigator agrees to allow inspectors direct access to all study records and source documentation.

11.2 STUDY MONITORING AND AUDIT

The ACCORD Sponsor Representative will assess the study to determine if an independent risk assessment is required. If required, the independent risk assessment will be carried out by the ACCORD Quality Assurance Group to determine if an audit should be performed before/during/after the study and, if so, at what frequency.

Risk assessment, if required, will determine if audit by the ACCORD QA group is required. Should audit be required, details will be captured in an audit plan. Audit of Investigator sites, study management activities and study collaborative units, facilities and 3rd parties may be performed.

12 GOOD CLINICAL PRACTICE

12.1 ETHICAL CONDUCT

The study will be conducted in accordance with the principles of the International Conference on Harmonisation Tripartite Guideline for Good Clinical Practice (ICH GCP).

Before the study can commence, all required approvals will be obtained and any conditions of approvals will be met.

12.2 INVESTIGATOR RESPONSIBILITIES

The Investigator is responsible for the overall conduct of the study at the site and compliance with the protocol and any protocol amendments. In accordance with the principles of ICH GCP, the following areas listed in this section are also the responsibility of the Investigator. Responsibilities may be delegated to an appropriate member of study site staff.

Delegated tasks must be documented on a Delegation Log and signed by all those named on the list prior to undertaking applicable study-related procedures.

12.2.1 Informed Consent

The Investigator is responsible for ensuring informed consent is obtained before any protocol specific procedures are carried out. The decision of a participant to participate in clinical research is voluntary and should be based on a clear understanding of what is involved.

Participants must receive adequate oral and written information – appropriate Participant Information and Informed Consent Forms will be provided. The oral explanation to the participant will be performed by the

Investigator or qualified delegated person, and must cover all the elements specified in the Participant Information Sheet and Consent Form.

The participant must be given every opportunity to clarify any points they do not understand and, if necessary, ask for more information. The participant must be given sufficient time to consider the information provided. It should be emphasised that the participant may withdraw their consent to participate at any time without loss of benefits to which they otherwise would be entitled.

The participant will be informed and agree to their medical records being inspected by regulatory authorities and representatives of the sponsor(s).

Inspection by regulatory authorities can be deleted for non-CTIMP studies. The Investigator or delegated member of the trial team and the participant will sign and date the Informed Consent Form(s) to confirm that consent has been obtained. The participant will receive a copy of this document and a copy filed in the Investigator Site File (ISF) and participant's medical notes (if applicable).

12.2.2 Study Site Staff

The Investigator must be familiar with the protocol and the study requirements. It is the Investigator's responsibility to ensure that all staff assisting with the study are adequately informed about the protocol and their trial related duties.

12.2.3 Data Recording

The Principal Investigator is responsible for the quality of the data recorded in the CRF at each Investigator Site.

12.2.4 Investigator Documentation

The Principal Investigator will ensure that the required documentation is available in local Investigator Site files ISFs.

12.2.5 GCP Training

For non-CTIMP (i.e. non-drug) studies all researchers are encouraged to undertake GCP training in order to understand the principles of GCP. However, this is not a mandatory requirement unless deemed so by the sponsor. GCP training status for all investigators should be indicated in their respective CVs.

12.2.6 Confidentiality

All, evaluation forms, reports, and other records must be identified in a manner designed to maintain participant confidentiality. All records must be kept in a secure storage area with limited access. Clinical information will not be released without the written permission of the participant. The Investigator and study site staff involved with this study may not disclose or use for any purpose other than performance of the study, any data, record, or other unpublished information, which is confidential or identifiable, and has been disclosed to those individuals for the purpose of the study. Prior written agreement from the sponsor or its designee must be obtained for the disclosure of any said confidential information to other parties.

Personal identifiable information will be kept and stored securely and separately from research data. Personal identifiable information will be kept and stored securely on an NHS server. This will be stored separately from the anonymised research data. Only researchers directly involved with the study will have access to this information.

The app won't store any personal identifiable information or information about our study. If a participant's phone gets lost or stolen, they can get in touch with the research team who can ensure that any data on the app can be deleted remotely.

Confidentiality will only be breached if a participant is identified as being at risk of coming to harm themselves or harming others. In such an instance, the benefit of ensuring safety and wellbeing outweighs the risk of breaching confidentiality.

12.2.7 Data Protection

All Investigators and study site staff involved with this study must comply with the requirements of the appropriate data protection legislation (including the General Data Protection Regulation and Data Protection Act) with regard to the collection, storage, processing and disclosure of personal information. Computers used to collate the data will have limited access measures via user names and passwords.

Published results will not contain any personal data and be of a form where individuals are not identified and re-identification is not likely to take place

STUDY CONDUCT RESPONSIBILITIES

12.3 PROTOCOL AMENDMENTS

Any changes in research activity, except those necessary to remove an apparent, immediate hazard to the participant in the case of an urgent safety measure, must be reviewed and approved by the Chief Investigator. Amendments will be submitted to a sponsor representative for review and authorisation before being submitted in writing to the appropriate REC, and local R&D for approval prior to participants being enrolled into an amended protocol.

12.4 MANAGEMENT OF PROTOCOL NON COMPLIANCE

Prospective protocol deviations, i.e. protocol waivers, will not be approved by the sponsors and therefore will not be implemented, except where necessary to eliminate an immediate hazard to study participants. If this necessitates a subsequent protocol amendment, this should be submitted to the REC, and local R&D for review and approval if appropriate.

Protocol deviations will be recorded in a protocol deviation log and logs will be submitted to the sponsors every 3 months. Each protocol violation will be reported to the sponsor within 3 days of becoming aware of the violation. All protocol deviation logs and violation forms should be emailed to QA@accord.scot

Deviations and violations are non-compliance events discovered after the event has occurred. Deviation logs will be maintained for each site in multi-centre studies. An alternative frequency of deviation log submission to the sponsors may be agreed in writing with the sponsors.

12.5 SERIOUS BREACH REQUIREMENTS

A serious breach is a breach which is likely to effect to a significant degree:

- (a) the safety or physical or mental integrity of the participants of the trial; or
- (b) the scientific value of the trial.

If a potential serious breach is identified by the Chief investigator, Principal Investigator or delegates, the co-sponsors (seriousbreach@accord.scot) must be notified within 24 hours. It is the responsibility of the co-sponsors to assess the impact of the breach on the scientific value of the trial, to determine whether the incident constitutes a serious breach and report to research ethics committees as necessary.

12.6 STUDY RECORD RETENTION

All study documentation will be kept for a minimum of 5 years from the defined end of study point. When the minimum retention period has elapsed, study documentation will not be destroyed without permission from the sponsor.

12.7 END OF STUDY

The end of study is defined as the last participant's last visit.

The Investigators or the co-sponsor(s) have the right at any time to terminate the study for clinical or administrative reasons.

The end of the study will be reported to the REC, and R+D Office(s) and co-sponsors within 90 days, or 15 days if the study is terminated prematurely. The Investigators will inform participants of the premature study closure and ensure that the appropriate follow up is arranged for all participants involved. End of study notification will be reported to the co-sponsors via email to resgov@accord.scot

A summary report of the study will be provided to the REC within 1 year of the end of the study.

12.8 INSURANCE AND INDEMNITY

The co-sponsors are responsible for ensuring proper provision has been made for insurance or indemnity to cover their liability and the liability of the Chief Investigator and staff.

The following arrangements are in place to fulfil the co-sponsors' responsibilities:

The Protocol has been designed by the Chief Investigator and researchers employed by the University and collaborators. The University has insurance in place (which includes no-fault compensation) for negligent harm caused by poor protocol design by the Chief Investigator and researchers employed by the University.

Sites participating in the study will be liable for clinical negligence and other negligent harm to individuals taking part in the study and covered by the duty of care owed to them by the sites concerned. The co-sponsors require individual sites participating in the study to arrange for their own insurance or indemnity in respect of these liabilities.

Sites which are part of the United Kingdom's National Health Service will have the benefit of NHS Indemnity. Sites out with the United Kingdom will be responsible for arranging their own indemnity or insurance for their participation in the study, as well as for compliance with local law applicable to their participation in the study.

13 REPORTING, PUBLICATIONS AND NOTIFICATION OF RESULTS

13.1 AUTHORSHIP POLICY

Suggested text only - amend as appropriate.

Ownership of the data arising from this study resides with the study team.

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Insert additional appendix and details or delete.