RESEARCH PROTOCOL

Full Title of Study: A qualitative study of healthcare professionals' perceptions about the uptake of a digitally mediated intervention for young people who have experienced online sexual abuse and its future integration into existing NHS and e-therapy infrastructure

Short Title of Study: i-Minds healthcare professionals qualitative study

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2. Summary

Title: A qualitative study of healthcare professionals' perceptions about the uptake of a digitally mediated intervention for young people who have experienced online sexual abuse and its future integration into existing NHS and e-therapy infrastructure

Objectives: The main aim of this study is to understand healthcare professionals' perceptions, as well as the barriers and enablers (and unintended consequences), relevant to the uptake of the digital intervention and its future integration into existing NHS infrastructure.

Design: A qualitative study which will utilise semi-structured interviews and focus groups to gather the views and opinions from up to 30 healthcare professionals who work with young people to provide mental health and / or sexual assault care in Greater Manchester, UK and Edinburgh, Scotland, and e-therapy providers.

Start date: July 2021

End date: January 2022

Study duration: 7 months

Funding: This project is funded by the National Institute for Health Research (NIHR) (Health Services and Delivery Research) programme (NIHR131848 - i-Minds: A digital intervention to improve mental health and interpersonal resilience for young people who have experienced online sexual abuse - a non-randomised feasibility study with a mixed-methods design). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Keywords: online sexual abuse; young people; abuse; healthcare professionals

3. Introduction

There is currently no evidence-based support offered to young people who have experienced online sexual abuse (YP-OSA). The National Institute for Health and Care Excellence (NICE) (1) has recognised as a research priority the identification of effective interventions for improving the wellbeing of YP-OSA and preventing further harm. Interventions aimed at improving mentalisation (the ability to understand the mental states of oneself and others) are increasingly applied to treat young people (YP) with varied clinical difficulties (2-4). YP-OSA are reluctant to seek in-person support and are generally comfortable receiving support online. The COVID-19 pandemic has exacerbated the already present risk and vulnerability of YP to OSA (5-8) and demonstrated the widespread value of digital interventions and the urgent need for digital therapeutic support for YP-OSA.

The current study contributes to the development of a digital mentalisation-based intervention aimed at improving mentalisation, interpersonal confidence and resilience in YP-OSA to reduce the risk for re-victimisation and future harm and equip them with the skills to manage distress that might result from OSA experiences. Interviews and focus groups will be carried out via phone or online with up to 30 healthcare professionals who work within NHS services delivering mental health and / or sexual assault support to YP in Greater Manchester and Edinburgh, and organisations that provide digital mental health care to YP. The interviews / focus groups aim to understand from healthcare professionals how to maximise the uptake, scaling up and integration of a digital intervention for YP-OSA in NHS and digital health provider settings which provide mental health and / or sexual assault support to young people. Data collected will be fed back to members of the research team responsible for the design of the intervention and the development of study information material and standard operating procedures of a subsequent study aimed at evaluating the feasibility, acceptability and usability of the intervention with YP-OSA.

4. Background

Young people (YP) use the Internet as a routine part of daily life. However, it can place them at risk of several forms of online sexual abuse (OSA). OSA involves being forced to take part in sexual activities, whether someone is aware or not of what is happening (for

example, being coerced into sharing sexual images of oneself, taking part in sexual activities via a webcam or smartphone, having sexual conversations by text, or being groomed, abused and exploited which may then lead to contact abuse) via any device connected to the Internet and across multiple platforms and applications. OSA can have serious effects on the development and mental health of young people (9-10). Furthermore, although there are similarities between the risks associated with and harms caused by offline and OSA, there is evidence of additional risks and unique social and psychological harms associated with OSA (11-13). This is recognised in the current NICE guidelines for responding to child abuse and neglect (1).

Not only is there no evidence-based provision for OSA, the demand for mental health support has significantly increased during the COVID-19 pandemic (14), generalist services (e.g. CAMHS) are overstretched and insufficiently resourced to meet the expanded demands for therapeutic input (15) and health and social care services have been put under even more pressure because traditional means of delivering face-to-face, clinic-based support have been limited or impossible. Child protection organisations have released recommendations on how to keep YP safe from OSA, but an evidence-based intervention that can be accessed by YP-OSA in a timely manner, even during crises whereby face-to-face, clinic-based delivery is not possible, to improve their wellbeing and protect them from future harm, is needed. There has been a dramatic expansion of digital health tools for YP, and evidence from research to demonstrate that digitally-mediated psychological interventions represent effective treatment options for improving the mental health and well-being of YP across a range of problems (16), including both behavioural and emotional difficulties (17). Furthermore, they have been found to be acceptable across genders (18) and safe with vulnerable YP (19). As most YP have access to and use the Internet, a digital intervention would significantly scale-up and accelerate access to therapeutic support for YP who have experienced OSA, potentially preventing problems caused by OSA exacerbating and YP being revictimized, whilst at the same time reduce burden on services.

We have received funding from the NIHR HS&DR programme to develop, in collaboration with YP-OSA, caregivers and professionals with relevant expertise and / or clinical experience, and using the current literature on OSA, a digitally-mediated mentalisation-based intervention that aims to support young people exposed to OSA. Before we develop the intervention, we need to gather information from healthcare professionals who work with YP within NHS services and services that provide digital mental health support to YP about how we should design the intervention to ensure uptake and engagement and so that it can be scaled up and integrated sustainably within services' existing routine care pathways. The current study aims to conduct interviews and focus groups with healthcare professionals to achieve this.

5. Study Aims and Objectives

The main aim of this study is to to understand healthcare professionals' perceptions, as well as the barriers and, enablers (and unintended consequences), relevant to the uptake of the digital intervention and its future integration into existing NHS and digital mental healthcare provision infrastructure. Specificallly, the study aims to find out from healthcare professionals:

- Their own experiences, if any, of delivering digital interventions.
- Their perceptions about the advantages and disadvantages of a digital intervention, what is currently offered in their service, how a digital intervention compares / fits in with existing practices (i.e. what is offered in their service).
- Who might benefit from the digital intervention and why.
- Their expectations about a digital intervention and what it should deliver / target.
- Their perceptions about the acceptability and perceived sustainability of identifying YP-OSA and referral routes to young people receiving the intervention.
- Their thoughts about the facilitators and barriers to uptake and continued engagement in the digital intervention within routine practice / care pathways.
- What support they think staff would need to implement the intervention.
- Their experience of scaling up interventions and how they went about doing this.
- Their perceptions about how a digital intervention could be scaled up and integrated into multiple services.

6. Study Design and Procedures

6.1 Design and Theoretical Framework

This study is a qualitative study employing semi-structured interviews and focus groups which will be guided by Normalisation Process Theory (NPT; 20-21). NPT is a widely used theory to explain the processes by which an intervention becomes, or fails to become, normalised into routine practice; it offers a framework for assessing the conditions in which interventions become practically workable in healthcare. NPT comprises four constructs (coherence, cognitive participation, collective action, reflecive monitoring) which are a set of propositions that will be used to explore perceptions, expectations, attitudes, challenges and unintended consequences towards integrating a digital intervention for YP-OSA in existing NHS service and digital mental health provider pathways.

6.2 Participants

Participants will be up to 30 healthcare professionals who work within NHS services that provide mental health and / or sexual assault support to young people (for example, Child and Adolescent Mental Health Services (CAMHS) and Sexual assault Referral Centres (SARC)) in Greater Manchester and Edinburgh or organisations that provide digital mental health support to young people (e.g. Kooth). Participants will be selected according to a purposive sampling framework to ensure optimal variation in the views, roles and relevant professional characteristics of healthcare professionals from the services we aim to recruit from. Healthcare professionals will be included in the study if they:

i) Work within an NHS service providing mental health and / or sexual assault / abuse support to young people including a Child and Adolescent Mental Health Service or Sexual Assault Referral Unit, or a service providing digital mental health support to young people (e.g. Kooth).

ii) Are 18 years or older.

iii) Are able to understand and speak English.

6.3 Recruitment

Potential participants who work in relevant NHS services (e.g. Child and Adolescent Mental Health Services (CAMHS) and Sexual Assault Referral Centres (SARCs) in Edinburgh and Greater Manchester and digital mental health providers (e.g. Kooth) that support young people will be identified with support from our collaborators within these services and local Clinical Research Networks.

With support from each research site contact, the researchers will email service managers of the relevant services of the NHS Trusts and digital mental health providers from where participants will be recruited, to ask their permission for the project flyer / poster (attached), participant information sheet (PIS) (attached) and informed consent form (ICF) (attached) to be circulated to staff via email, their website, social media (e.g. twitter), newsletters, weekly bulletins, announcements etc.

The researchers will also ask for permission to attend departmental / team meetings (remotely). At these meetings, a brief presentation (attached) will be given to inform staff about the aims of the project, why they are being asked to take part, what taking part will involve and how the data will be used. Staff who attend the meeting will be given the opportunity to ask questions and will be informed by the researchers that, if they are interested in taking part, they should email the researchers for the PIS and ICF or can provide their email address at the end of the information session so that the researchers can email them the relevant documents.

A flyer / poster will be circulated via the Complex Trauma and Resilience Research Unit's (C-TRU) website (which is hosted by the University of Manchester) and twitter page and via the website and by COMMS (e.g. emails, announcements, newsletters, weekly bulletins) of the sponsoring NHS Trust (Greater Manchester Mental Health NHS Foundation Trust) from which participants will be recruited.

Potential participants who are interested in taking part in the study will be asked to contact the research team directly. All potential participants will be sent the PIS and ICF (via email,

fax or regular mail) when they express an interest in taking part in the study if they have not already received them.

The researcher(s) will explain in concise and clearly understandable terms to all persons invited to take part:

1. who is conducting the research
2. why it is being conducted (including the true purpose of the research)
3. why they have been asked to take part
4. what it requires of them (including the amount of time they will be required to commit and what they will have to do)
5. what will happen to the data they provide
6. whether and how their anonymity and confidentiality will be maintained
7. that their participation is voluntary and they are free to withdraw at any time without detriment (where possible)

The researcher will ensure that participants are given the opportunity to discuss the study over the phone / online conferencing platofmr (e.g. Microsoft Teams / Zoom / Skype) and have their questions answered.

Potential participants will be offered at least 24 hours to consider all the information provided before written consent can be obtained.

A date for the interview or focus group will be scheduled over the telephone / online conferencing platform (and confirmed with the participant via email) once participants confirm that they are satisfied with the information described in the PIS and ICF and would like to take part in the study. At the time the interview / focus group is scheduled, participants will be asked if they have a preference in relation to whether they take part in a one-to-one interview or a focus group. They will also be asked if they have a preference in relation to whether they would like the interview or focus group to take place over the telephone or via online conferencing (e.g. Zoom or Microsoft Teams). The option to take part in a focus group may depend on whether other participants have opted to take part in

this way and on their availability. Participants will be asked to have the PIS and ICF in front of them when they take part in the interview / focus group.

6.4 Informed Consent

Informed consent will be obtained orally using an oral consent script (attached), and in writing (if feasible). Oral consent will be recorded using an encrypted digital audio recording device or an online conferencing platform. Obtaining consent will take 5 minutes per participant. Using the oral consent script, the following steps will be taken to obtain informed consent. The researcher will ensure that oral consent is recorded or witnessed.

1. At the beginning of the interview / focus group, the researcher will ask the participant to confirm that they have read the PIS and ICF, have received sufficient information about the study and have the documents in front of them. Participants will be asked if they have any questions about the information in the PIS and ICF; questions will be answered by the researcher before consent is obtained and interviews or focus groups begin. Participants will be reminded that consent will be obtained verbally and in writing. The researcher will check the participant is satisfied to proceed with consent and taking part in the study.

2. If the participant is satisfied to proceed, the researcher will write the time, date and name of the participant on their version of the consent form in front of them.

3. The researcher will start the audio recording and state the name of the project, their own name, the date and time. Participants will be asked to state their name for the recording.

4. Participants will be asked to indicate whether they agree to the statements in the consent form and are happy to participate under the conditions described in the ICF. The researcher will note their responses on the form in front of them and then sign the form.

5. Once consent has been audio recorded, the researcher will inform the participant that they are ending recording of the consent process.

6. If practical and feasible, after interviews and focus groups are completed, participants will be asked if they can email, fax or mail their copy of the signed consent form to the researcher for the study's records.

7. Audio recordings of the consent process will be recorded using an encrypted device / online conferencing platform and as a separate file to the main interview or focus group. They will be stored securely on password protected computers and on the University's or Trust's secure server in password protected files separately to interview and focus group audio recordings. Recordings of consent will be deleted from the device used to make the recording immediately after they have been uploaded. Recordings will be kept as long as signed consent forms would be stored.

Participants can withdraw consent at any time without giving any reason, as participation in the research is voluntary, without their care or legal rights being affected. If a participant loses capacity to consent during the study, the participant will be withdrawn from the study. Identifiable data alreadu collected with consent will be retained and used in the study. No further data will be collected or any other research procedures carried out in relation to the participant.

6.5 Data Collection

Once informed consent has been obtained, participants will be asked to provide demographic information (gender, ethnicity, number of years working in mental health / sexual assault care and the service they currently work in, job title and role) using a brief demographic questionnaire. This will take 5 minutes. They will then be interviewed via a one-to-one semi-structured interview or focus group. This will last approximately 1 hour. Interviews / focus groups will be audio recorded using an encrypted digital recording device or online conferencing platform. Audio-recordings will be uploaded to the University's or Trust's secure server in a password protected folder using a password protected computer immediately after interviews / focus groups have finished and will be deleted from the recording device as soon as they have been stored securely. Audio recordings of consent and interviews / focus groups will be stored separately.

At the end of interviews / focus groups, all participants will be thanked for their participation and debriefed, which will include signposting to further support should this be required, and information about what will happen to the results of the study. Participants will be given the opportunity to ask further questions and the researchers will ensure they are answered satisfactorily. Debriefing participants will take up to 10 minutes, depending on whether the participant requires further support or not.

7. Data handling and management

Data will be handled and stored in accordance with GMMH, NHS Lothian, University of Manchester and University of Edinburgh guidance, General Data Protection Regulation, the NHS Caldicott Principles and the Research Governance Framework for Health and Social Care (2005). The study Data Management Plan (DMP) will be adhered to by all members of the research team and throughout the duration of the project. The PI will have control of and act as custodian of the data generated by the project. All data generated by the study will be stored for a minimum of 5 years.

7.1 Confidentiality

Participants will be assigned with a unique study ID immediately following consent to take part in the study. An electronic password-protected log matching names to unique study IDs will be stored separately from all the research data. Unique study IDs will be used to label demographic questionnaires, audio-recordings and transcripts. Measures will be taken to exclude all personal information from interview recordings. Transcripts will not contain any identifying information. A database storing demographic information about participants will be password protected and use unique study IDs. An electronic password-protected pseudo-anonymised log containing participant contact details including their work email address and phone number will be stored separately from all the research data. Role-based permissions will be assigned and recorded via a delegation log to ensure that each member of the research team can only access the data they need to; in this way access to personal data including names and contact details will be restricted only to users who need to be able to contact participants. Passwords for data files will only be given to those who have been given permission to access the data as indicated in the delegation

log. Pseudonymised recordings of the interviews / focus groups will be transcribed by a research worker or an approved transcription service. All recordings will be transferred and stored securely, and the transcription service will follow GDPR regulations (2018). Issues relating to confidentiality will be addressed and potential participants will be advised of the limits of confidentiality (i.e. that the researcher will have a duty to inform healthcare professionals if the participant discloses information which highlights any safeguarding or risk issues). Participants will provide informed consent to data being collected on the understanding that information will be confidential and stored in a secure manner (in a locked room in a locked filing cabinet) for the duration of the study, or for longer, only if specific consent has been sought and given for this. Participant consent forms will be retained, kept confidential and stored securely. All identifiable data will be destroyed following a period of 5 years (as determined by relevant information governance policies) after the completion of the study.

7.2 Use of audio-recording devices

The process of obtaining oral consent and semi-structured interviews and focus groups will be audio-recorded using an encrypted digital audio-recorder or via an online conferencing platform (e.g. Zoom and Microsoft Teams). This to ensure a record of informed consent is obtained and so that interviews and focus groups can be transcribed for subsequent qualitative data analysis by a member of the research team (or someone external from an approved transcription service) in adherence with rules on confidentiality and data protection. Oral consent audio-recordings will include the short title of the study, the date, time and name of the researcher taking consent being stated, and the participants stating their name and whether they agree to the statements read out to them by the researcher from the consent form (and thus confirming they have received sufficient information about the project, understand why they have been invited to take part, why the study is being conducted, what it will involve and are happy to take part). Interview and focus group recordings will include the title of the study, the date, time, name of the researcher doing the interview and unique ID of the participant. The study will adhere to the joint guidance on secure audio recording issued by The University of Manchester, The University of Edinburgh and participating NHS Trusts, including the Sponsor.

All audio-recordings will be uploaded to the relevant study folder on the NHS Trust's or University's secure network drive as soon as possible following the recording. Once the upload has occurred, all audio-recordings will be deleted from the recording device. Oral consent will be recorded on a separate audio-recording to interviews and focus groups and will be stored for as long as written consent forms would be stored. When not in use, audio-recording devices will be stored in a locked cabinet within a locked office or a locked bag where offices are not in use due to the COVID-19 pandemic.

7.3 Use and storage of personal data

Personal data will include participants' names, work email addresses and / or telephone numbers and information collected about participants via the demographic questionnaire (e.g. gender, ethnicity, number of years working in mental health / sexual assault care and the service they currently work in, job title and role). Work email addresses and telephone numbers will be used by the research team to contact participants to send them the study documents (e.g. PIS and ICF) and arrange and conduct an interview or focus group. Participant contact details will be stored for up to 3 years after the study has been completed for the purposes of inviting participants to take part in relevant research in the future. The PIS states that participants will be asked to consent to their name and work contact details being retained for the purposes of sending them a summary of the findings of the study and contacting them about potential participation in relevant future research. It is indicated in the ICF that this is optional and is not required for participants to take part in the study. It might be necessary for participants' names and contact details to be shared between the research team at the different sites (i.e. Manchester and Edinburgh) so that the task of conducting the interviews and focus groups can be shared amongst the researchers and to avoid delays to data collection (for example, a researcher in Manchester might need to conduct an interview with a participant recruited in Edinburgh if, for any reason, the researcher based in Edinburgh is not available and vice versa). All personal data will be stored electronically using unique study identifiers and password protected files on University and / or NHS Trust secure server networks at both study sites and will be accessible only by researchers identified on the delegation log as having permission to do so.

7.4 Electronic storage and transfer of data

Electronic data for this study will include:

- participant contact details
- participant names matched with their unique study IDs
- completed participant demographic questionnaires
- database recording responses to the demographic questions
- audio-recordings of oral consent
- audio-recordings of interviews and focus groups
- scanned copies of consent forms completed by the researcher (oral consent)
- scanned copies of consent forms completed by the participant (written consent)
- transcripts of interviews and focus groups

All electronic data will be stored on the corresponding site NHS Trust (i.e. GMMH / NHS Lothian) and / or University's (i.e. University of Manchester / University of Edinburgh) shared and secure server network drive using password protected NHS Trust and / or University computers (including laptops). Access to electronic data will be restricted to members of the research team except for the purposes of audit by relevant organisations including NHS Trusts and Universities involved and the Sponsor. Participants will be informed of this in the PIS and ICF. Access to anonymised demographic data and interview and focus group transcripts may be shared with researchers outside of the research team for th purposes of secondary data analyses (e.g. to answer other related research questions), including education studies. Participants will be informed of this in the PIS and ICF. All files where possible will be password protected / encrypted. All electronic data listed above will be kept in files separate from each other. Interview and focus group audio-recordings will be deleted once transcription has taken place.

Anonymised data (e.g. interview and focus group audio-recordings and transcripts) may need to be transferred between sites (e.g. from Edinburgh to Manchester or vice versa) using secure and encrypted methods agreed with both sites, such as encrypted emails via the nhs.net email system or an encrypted USB via courier. Data sharing agreements will be put in place as appropriate with relevant organisations, as part of study setup. Encrypted digital audio-recordings of interviews and focus groups may be sent to an NHS

Trust / Sponsor and / or University approved external company for transcription. Digital audio recordings and their transcripts will be identified only by a unique research ID. They will be sent by email using encrypted files.

7.6 Physical storage of data

The small number of manual (paper) files will be kept in a locked filing cabinet in a locked office at both study sites and will be accessible only by researchers identified on the delegation log as having permission to do so.

7.7 Data analysis and use of data in publications

Data generated by the study will be analysed using NHS Trust and / or University computers by the research assistants under the supervision of senior members of the research team (i.e. PI, project manager, Co-Is). Direct quotations from the interviews and focus groups may be published. These will be anonymised to ensure participants are not identifiable. No identifiable data will be written up for publication.

8. Data Analysis

8.1 Sample Size

There is no specific formula for determining a qualitative study sample size. We have anticipated we will reach data saturation with up to at 30 participants.

8.2 Descriptive Statistics

Descriptive statistics will be used to describe the demographics of the sample.

8.3 Qualitative Data Analysis

We will use a qualitative Framework approach to analyse the data. We will first inductively analyse the data using thematic analysis, and then deductively code the inductive themes generated from the thematic analysis in a coding frame alongside normalisation process theory (NPT) (described in Section 6.1). Data collection and analysis will take place concurrently and fed back to members of the team responsible for the design of the digital intervention and the development of study information material and standard operating

procedures (SOPs) of the feasibility study being conducted in our larger programme of work.

9. Data monitoring and quality assurance

The study will be subject to the audit and monitoring policies and procedures of the University of Manchester, University of Edinburgh, Greater Manchester Mental Health NHS Foundation Trust (Sponsor) and NHS Lothian.

10. Patient and Public Involvement and Engagement

The design of the research and application for funding included input from YP-OSA and professionals who work within services that support young people. As part of the larger project, we will have a Young Persons Advisory Group (YPAG), composed of young people who have experienced online sexual abuse, and a Parent and Professionals Advisory Group (PPAG), composed of both professionals who work within a range of different NHS, local authority and voluntary sector services locally (in Greater Manchester and Edinburgh) to support young people, and professionals who work within national child protection and law enforcement organisations / agencies, social media providers or educational institutions and have expertise in online sexual abuse.

11. Ethical considerations

This study presents minimal risks to participants and researchers.

Discussion of sensitive / upsetting topics - Participants

Participants will only be asked questions about the online intervention and its potential integration into services. They will not be asked to discuss specific cases or highly sensitive, emotive or distressing topics. However, if for any reason a participant does become distressed during the interview or focus group, the researcher will follow a Distress Management Protocol (attached). In short, the interview or focus group will be stopped immediately. The participant will be reminded that they can withdraw from the study at any time. The participant will only continue participating in the interview / focus group if they feel comfortable doing so. The researcher will debrief the participant at the end of their participation; if a focus group and a participant decides not to continue taking

part, the researcher will check that the participant is OK and debrief them with a follow-up phone call once the focus group has finished. The researcher will discuss with the participant whether they might wish to arrange a meeting with their line manager or another member of staff they feel comfortable discussing this with, and will be signposted to places where further support can be sought.

Discussion of sensitive / upsetting topics - Researchers

The questions the researchers will be asking in the interviews or focus groups will not include highly sensitive, emotive or distressing topics. However, if the researchers do feel distressed, they will follow the Distress Management Protocol. In short, a debrief meeting with their line manager or a senior member of the research team with whom they feel comfortable discussing this with will be arranged. The research assistants will also receive appropriate training in distress management from their local trusts and / or an experienced Clinical Psychologist.

Management of disclosures

If a participant discloses something which raises serious concerns about their safety or the safety of others, it may be necessary to break confidentiality and inform relevant parties. This will be discussed with the participant during the consenting process.

Physical safety of researchers

Researchers will conduct telephone or online interviews and focus groups from their home or place of work (Greater Manchester Mental Health NHS Foundation Trust / NHS Lothian). This presents minimal risk to their physical.

Informed Consent

Oral and written informed consent will be obtained from all participants.

12. Statement of indemnity

An NHS indemnity scheme will apply in the event that participants are harmed as a result of the management of the research.

An NHS indemnity scheme and University of Manchester and University of Edinburgh schemes will apply in the event that participants are harmed as a result of the design of the research.

An NHS indemnity scheme and scheme from a non-NHS site will apply in the event that participants are harmed as a result of the conduct of the research.

13. Publication policy

It is intended that the results of the study will be reported and disseminated at national and international conferences and in peer-reviewed scientific journals. They will be made available to participants and clinical teams in an accessible format, on the study and Complex Trauma and Resilience Research Unit website. They will also be accessible in print and digital media and presented at stakeholder events.

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