How to Run a Smartphone EMA Study For Young Adults with Rare Genetic Conditions

PRESENTED BY POPPY, NAVIDA AND KATE

CONTENTS

CONTENTS: INTRODUCTION

THESE GUIDELINES WERE WRITTEN BY

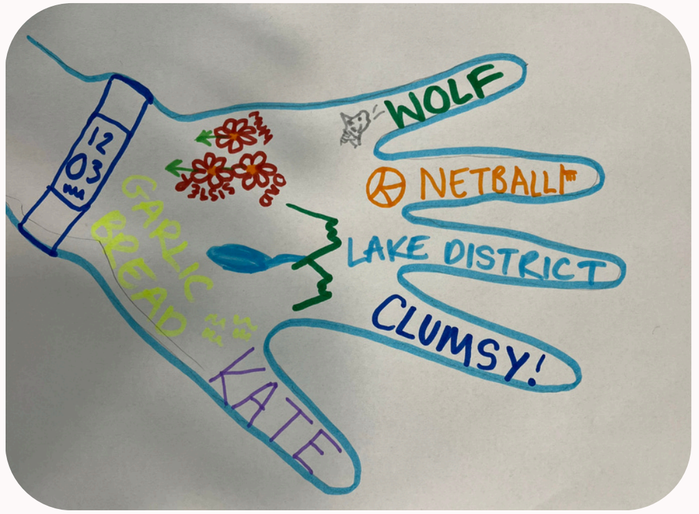
Navida

Navida is an MA graduate at Birkbeck, University of London. Her favourite things include drawing and painting and she loves her pet dog LEAH!

Poppy

Poppy is a volunteer speaker for the Blue Cross. Her favourite things include reading manga and singing and loves her 2 dogs and tortoise.

Kate



Kate is a PhD researcher at King's College London. Her favourite things include playing netball, garlic bread and walking up mountains!

WHY ARE THESE GUIDELINES NEEDED?

Kate started her PhD in October 2022 looking at how to use smartphone ecological momentary assessment (EMA) to understand the daily experiences of young adults with a rare genetic disease.

However she had never used smartphone EMA before and struggled to find guidance on how to run the study successfully with young adults with a rare genetic condition.

So she hired two young adults with a rare genetic condition to help her design the study.

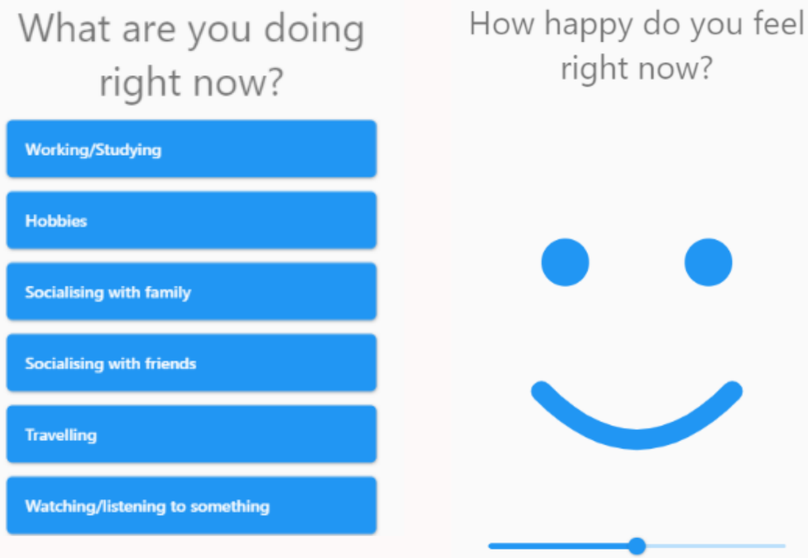
Navida and Poppy acted as advisors and met online and in person with Kate over a number of months to discuss how to run an EMA study.

These guidelines are a result of this advisory group and have been co-produced between Navida, Poppy and Kate.

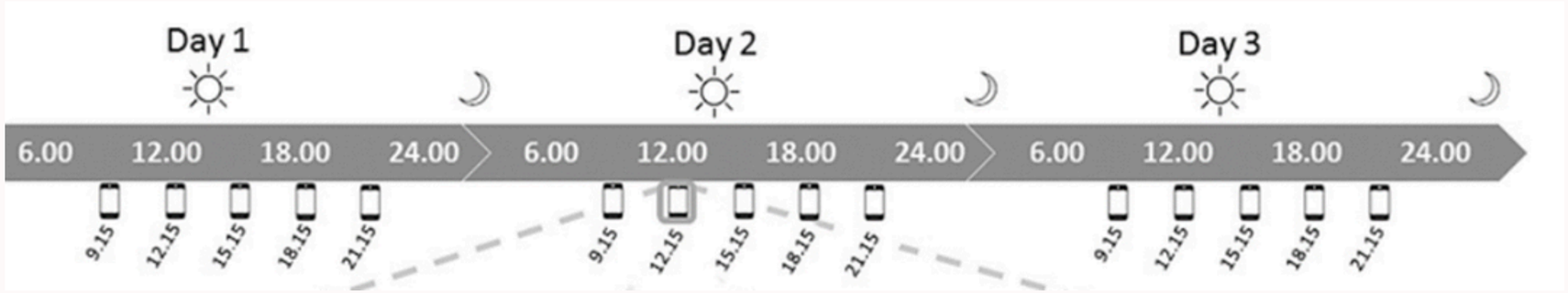
WHAT IS AN EMA STUDY?

- EMA stands for Ecological Momentary Assessment.
- EMA is a way of understanding an individual's everyday experience or symptoms .
- Individuals receive repeated notifications on their smartphone to answer questions about their experiences, feelings, and thoughts ‘in the moment’.

Example EMA questions



Example EMA schedule



WHY USE SMARTPHONE EMA?

- You report your feelings ‘in the moment’. This can be easier than trying to remember how you felt in the past e.g. How did you feel last Tuesday at 6pm?’
- You report more of your feelings. You report your feelings a few times a day rather than being asked once ‘How have you been feeling over the last two weeks?’
- You report your feelings in real life. So when you are at home, work, school, and other places like grocery shopping. Not just in a doctors room or hospital room.
- You can use a familiar device such as your own smartphone or smart device (tablet).

WHY USE SMARTPHONE EMA FOR YOUNG ADULTS WITH A RARE GENETIC CONDITION?

If you have a rare genetic condition...

1. You often have to travel far for specialised support.

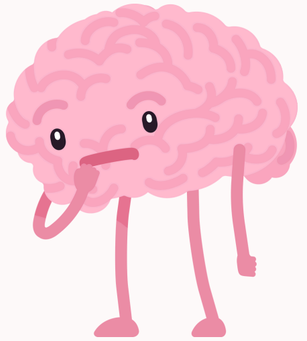
- Using your phone to record and pass on your feelings and experiences may mean you don't have to travel as much to get help.

2. You might struggle with remembering things that happen to you and how you felt.

- Just remembering what has happened to you in the last few minutes might be easier than trying to remember over days or weeks.

3. You might have lots of health symptoms and have to take lots of medication.

- Using EMA may help you understand how all these things affect you.



GUIDELINES AIMS

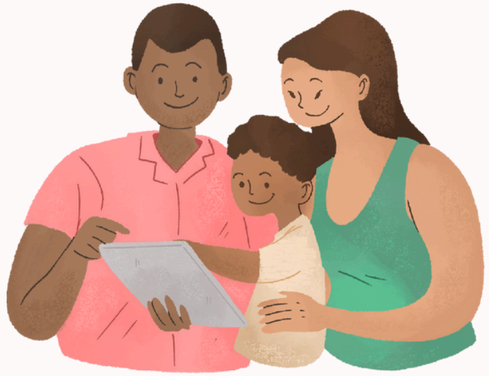
1. To help young adults with rare genetic conditions take part in EMA studies.

2. To help researchers run sucessful EMA studies with young adults with rare genetic conditions.

3. To make it clear for participants and researchers what will happen in an EMA study.

WHO ARE THE GUIDELINES FOR?

- Young adults with rare genetic conditions
- Parents and caregivers of young adults with rare genetic conditions
- Schools and teachers
- Researchers
- Healthcare professionals



FOR PARTICIPANTS

CONTENTS: FOR PARTICIPANTS

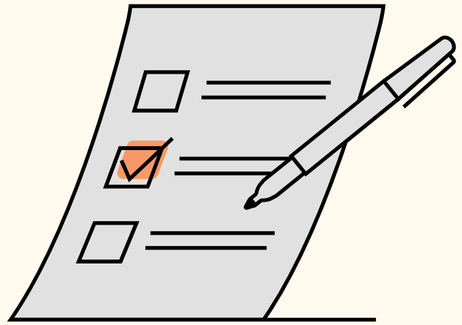
WHAT WILL HAPPEN IN A EMA STUDY?

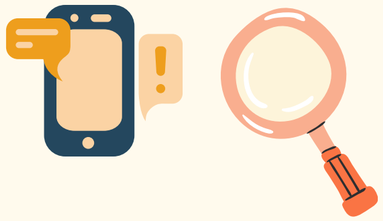
WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY?

SCREENING

- You have seen an advert asking you to participate in a smartphone EMA study.
- You will have a conversation, likely over the telephone, with a researcher who will explain the study.
- If you are not sure about the study you can ask the researcher questions.

- If you want to take part you will be asked to fill in a consent form. This will ask you for your permission to take part in the study.
- You may complete some questionnaires asking for information about yourself and how you have been feeling recently.





WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY?

TRAINING

- You will then have a ‘training session’ where a researcher will show you the EMA app and tell you what will happen.

- This might happen online over video call or face-to-face.

In the training session:

- You will be told the purpose of the study.
- For example: To understand how your mood changes throughout the day.
- This may help understand your genetic condition and how it affects you.

WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY?

TRAINING

- You will be shown how to download the app onto your phone.
- You will be shown all the questions you will be asked
- You will be shown how to answer each question and what it means.
- You might be asked to answer some example questions.

WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY

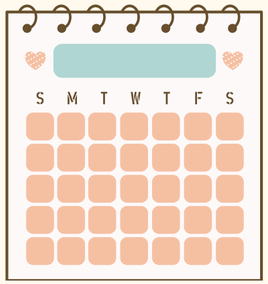
TRAINING

- You might be asked to choose some things about the way the app will run
    - Rewards.
    - How the questions are worded.
    - What each notification says or sounds like.
- You might be asked questions about what time you get up in the morning, go to bed and what you do during the day.
- This will help the researcher set up when the questionnaires will be sent to you.

WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY

TRAINING

- It is common for them not to tell you exactly when the questionnaires will be sent.
- You will then decide what dates you will use the app for.
- You might be given a ‘participant manual’ that will have everything from the training session in.



WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY

USING THE APP

- You will then use the app for a certain amount of days.
- You will answer a number of questionnaires throughout the day.
- You might not know what time the questionnaires will appear, it may be random.

WHAT WILL HAPPEN IN A SMARTPHONE EMA STUDY

AFTER THE APP

- After you have finished using the app, the researcher might ask you questions:
    - About how you felt using the app,
    - What you liked about the app,
    - What you didn't like about the app.
- They might also ask you to complete some final questionnaires.

ADVICE

1) It is normal to feel nervous about using the app, but don't worry, you will get used to answering the questions and using the app.

2) If you are unsure about anything ASK FOR HELP. The researchers will be there to answer your questions and provide more training if you need it.

3) Try not to give up on using the app and answering the questions. It is to help the research of the condition you have.

4) If you are struggling to use the app, ASK FOR HELP. The researchers would prefer to try and change how the app works to suit you rather than you stop using it.

CHALLENGES YOU MAY FACE

1) The app and questions might be confusing.
You will get used to answering the questions and you can also ask the researchers for help.

2) The app might not work the way it should.
Tell the researcher and they will help you

3) You might forget how to use the app.
Look at the guidelines and manual the researcher has sent you.

4) You might forget to answer some questionnaires.

Don’t worry this is ok, the researchers know this may happen.

5) You might not realise the questionnaires are ready.

Make sure you check your phone. But don’t worry, if you do miss one, that is fine.

6) You might not be able to use your phone at certain times, during work or school.

Tell the researcher this might happen and tell them your schedules so that they can try to arrange the questionnaires to your timetable.

FINAL TOP TIP

ALWAYS ASK FOR HELP

For Researchers

Contents: Researchers

Before you start

Smartphone EMA in clinical populations is still relatively new. If you work in genetic diseases and especially rare genetic diseases, it is likely you might be one of the first to run an EMA study.

Therefore it is really important to understand how the young adults with the condition can manage with EMA.

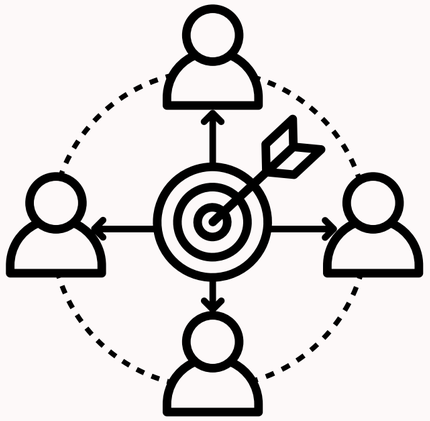
Before you start

There are lots of different things to consider:

1. The type of app to use.
2. To include cognitive or motor games.
3. How many questionnaires a day.
4. How many questions per questionnaire.
5. How many study days.
6. What personalisation might be needed.
7. What support participants might need from others to use the app.
8. What limits to put on the questionnaires, such as how long they have to complete them.
9. What is the best way to recruit your participants.

To help you decide on these parameters, you will need help. You can get this help from Patient and Public Involvement.

Patient and Public Involvement



Patient and Public Involvement (PPI) in research means how patients, participants or other people with relevant experience contribute to how a research study is run.

PPI should be used for all research, even laboratory studies. However, it can be especially useful for EMA research as EMA studies requires a high level of interaction from participants.

PPI should be considered at all research stages from the design through to dissemination and evaluation.

You can read more abut PPI on the NHS Health Research Authority website.

https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/

PPI in smartphone EMA can be done via multiple ways and at multiple times throughout your research study timeline. Below are some examples of PPI used in EMA and related research.

Exploration

- PPI using focus groups and interviews to understand potential participants attitudes and needs towards smartphone EMA.
  - *'Developing mHealth Remote Monitoring Technology for Attention Deficit Hyperactivity Disorder: A Qualitative Study Eliciting User Priorities and Needs' (Simons et al., 2016)*

Design

- Advisory or stakeholder groups who advise throughout the design process
  - *'Involving stakeholders in the design of ecological momentary assessment research: An example from smoking cessation' (Soyster & Fisher, 2019)*

Pilot Testing

- Using PPI to pilot test and receive feedback on your EMA protocol.
  - *'Development of a Mobile App for Ecological Momentary Assessment of Circadian Data: Design Considerations and Usability Testing' (Woolf et al., 2021)*

Dissemination

- Using PPI to guide how you will share or disseminate the findings from your research.
  - *'An innovative toolkit: increasing the role and value of patient and public involvement in the dissemination of research findings' (McNichol & Grimshaw, 2024)*

Patient and Public Involvement

It is important to get a wide range of experiences in your PPI.

Young adults with genetic conditions may vary significantly in ability and life stages. This can affect how they participate in research.

It may be useful to also hear the opinions of people supporting young adults with genetic diseases as well, such as parents, carers or teachers.

"Involving adolescents with intellectual disability in the adaptation of self-reported subjective well-being measures: participatory research and methodological considerations" (Davison et al., 2022)

Recruitment

You can recruit for an smartphone EMA study like any other research study i.e adverts, social media etc. However there are a few things things to think about

EMA might be a bit complicated to explain on an advert. It may be best to use wording like ‘smartphone assessment’ or ‘remote monitoring’ on adverts. You can then explain what EMA is later in the screening stage.

Make sure to include:

- How many questionnaires a day and how many days of assessment the participants will be asked to complete.
- The eligibility criteria regarding smartdevices - are you providing a smart device or do the participants have to own one already.
- If you will be compensating participants for their time.

Assessment with Smartphones in Rare Genetic Diseases:

A FEASIBILITY STUDY

Are you aged between 16 and 35 and have a rare genetic disease?

Do you own and use a smartphone (a phone that can download apps)?

We would like to invite you to our research study. You will be testing out a new smartphone app that can help track the day-to-day feelings or symptoms of young adults with rare genetic diseases may face.

Taking part involves...

- Completing some online questions and assessments
- You will test the app out for 10 days.
- The app will ask you to complete 4 questionnaires a day.
- You will be asked questions about what you liked/disliked about the app.

You will be compensated with a shopping voucher.

For more infomation visit our website: www.-----.co.uk

If you would like to take part...

Please click the below link to provide your contact details and a member of the team will be in touch.

Training

It is very important to provide training for the participants on how to use the smartphone EMA app.

This will ensure:

- The participants feel confident they can use the app for the required time and are less likely to drop out.
- The participants answer the questionnaires in the right way i.e making sure they answer as to what they were feeling just before the questionnaire, not while answering the questionnaire.
- The participants know what to do if something goes wrong.

Be aware participants may need different levels of training. Some may manage with a 20 minute phone call where others might need an hour video call with lots of examples. It is important to plan accordingly for this in your protocol.

Training

- It might be useful to provide a ‘manual’ that the participants can keep during the time of the study. This can remind them of what you go through in the training.
- Make sure to provide contact information that the participants can use if they have any difficulties or questions.
- Make it clear to the participants how you will handle contact during the EMA study. For example if you work part time, make sure to be clear on how long it might be until you get back in contact with the participant to sort the problem. This will help alleviate any stress for the participant if they can’t use the app when they were meant to.
- Adequate training will help the participants take part in your research and improve the quality of your data!

Progress

Whilst the young adults are using the app. It’s important to keep an eye on their progress.

Make sure to define in your protocol how you will ‘check in’ with the participants. This will make sure it is consistent with every participant. This might include:

- A check in on day 1 to confirm there were no technical difficulties.
- A check in if a participant hasn’t answered a questionnaire in a number of days.
- A check in halfway though the EMA protocol.

These could be done via email or telephone.

Make sure to contact the participant once they have finished the smartphone EMA to confirm they have completed the EMA.

Supporting the young person during the EMA

- Be flexible. Young adults with rare genetic conditions have to manage a lot of things in their life which might be quite new to them.
- Make sure you offer training sessions and appointments at a time suitable for them. This could be after work or college.
- Be mindful of the ability of the young adults. This could vary and so your communication style may need to change.
- Use their existing support network. Ask if the young adults want help from their parents, partners or other key support people during the study.
- Make sure to meet with their key support person to ensure they understand what their young adult needs to do for the study.

Sharing results

- You do not need to share the results of the EMA with individual participants.
- However it can be nice for the participants to see some of their results if they are interested.
- Receiving results should be optional, if participants don’t want their results, don’t share them.

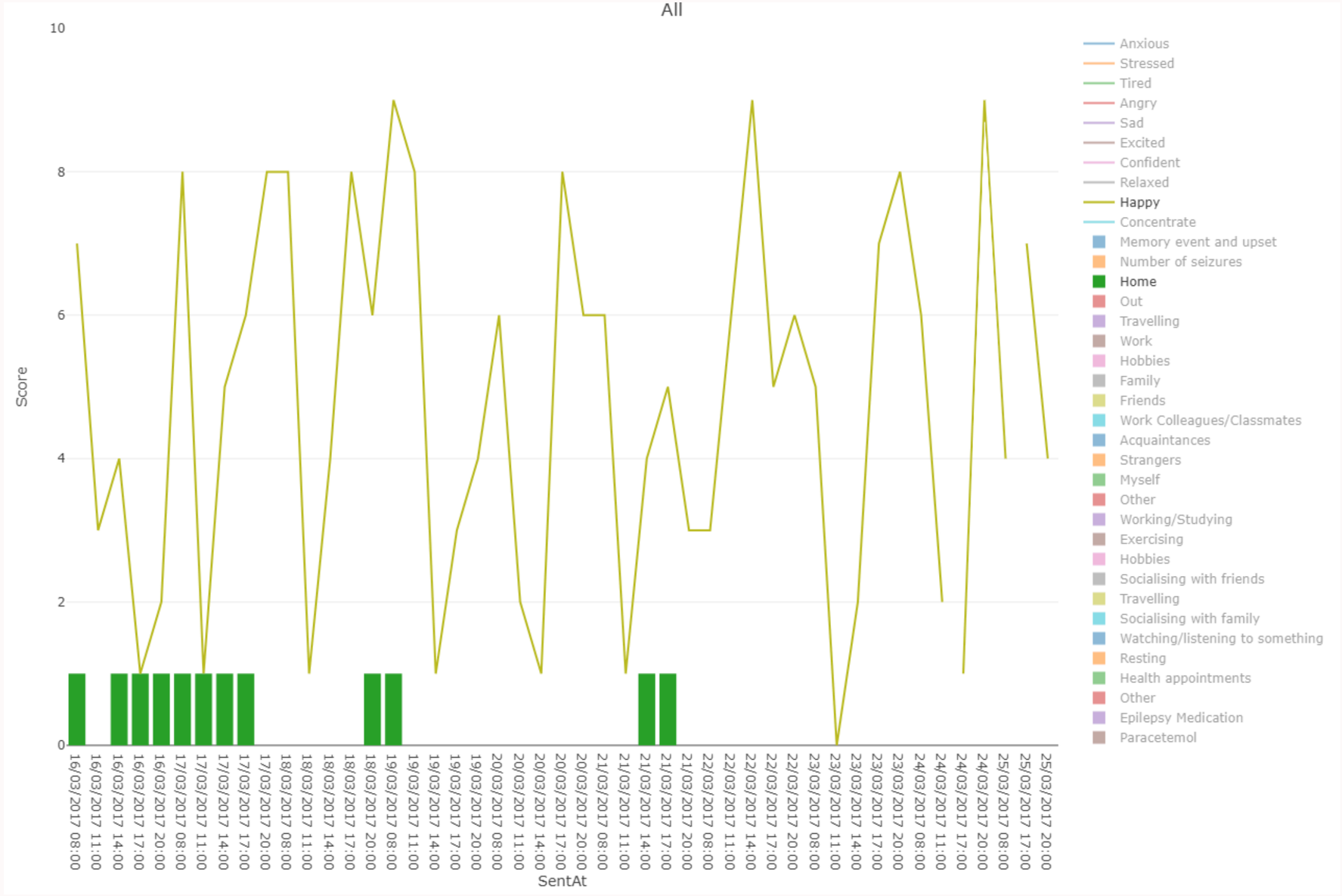
Sharing results

- Be wary that providing results may become ‘interventional’. If you are sharing results in order to see any behaviour or emotional change, this may be classed as EMI or Ecological Momentary Intervention and have different ethical considerations.

- To avoid this, only share results at the end of the study and focus on positive or descriptive data. For example “you spent this much time at home compared to at work” or “you rated yourself happier when you were at home compared to at work”.

- EMA data can be very complicated so share the EMA results in a way that the participants can understand them.

Sharing results - Example



- This graph was created using the Plotly package on R studio.
- Participants can click on individual questions and compare their results.

Sharing Overall Results

- For the overall results of the study, you should offer to participants if they would like to receive this.
- This may be important to sustain motivation in young adults with rare genetic conditions to continue to participate in research.
- PPI can help advise or co-develop the best way to share results in a way participants can understand.
- Examples could be a poster, infographic or blog post.

Example dissemination:

"Using Experience Sampling Methods to Understand Everyday Experiences of Adults with Intellectual Disability" (Wilson et al., 2019)

Ethical Considerations

Risk

- If you are monitoring negative emotions or any risk behaviour during the EMA, you have a duty of care for each participant.
- Be clear in your protocol what you will do if, whilst during the research study, participants report negative outcomes such as consistent low mood or negative thoughts about harming themselves.
- Be clear to the participants in the information sheets and screening stage about what will happen if this occurs.
- Make sure you ask for consent if you need to share their results with anyone as part of your risk protocol.

See examples for PIS and consent forms on the next slide.

Ethical Considerations

Example PIS

“If at any time during the study, you disclose severe low mood or anxiety and the research team have concern regarding your level of emotional distress, we will get in contact with your GP. This is to ensure you have ongoing suitable support. We will tell you that we are contacting your GP and the reasons why.”

Example consent form

“I agree that my GP may be contacted if any unexpected results are found in relation to my health or if the research team has a concern regarding my level of emotional distress.”

Top Tips

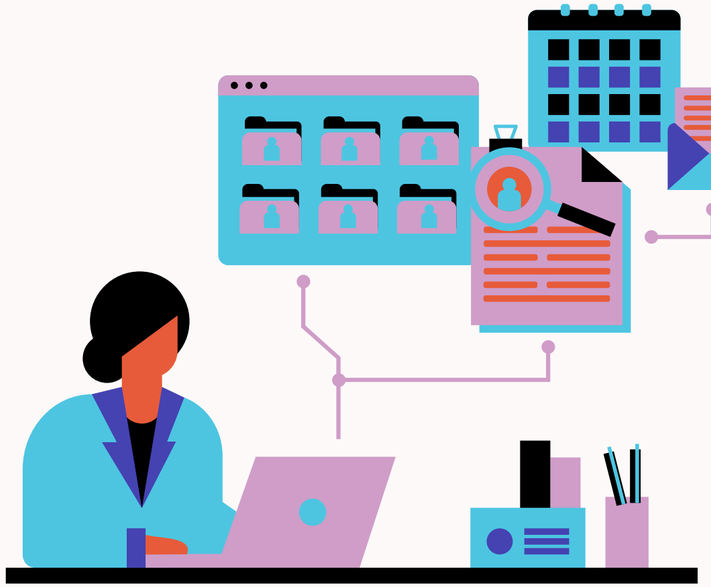
What to do

- Use PPI throughout your research to increase your chances of your EMA research being acceptable and feasible.
- Be aware their support network may have changed since becoming young adults. Don’t assume parents are the primary support network.
- Acknowledge life constraints which may stop young adults from responding to the EMA, whether this could be work, college or other commitments. Support them in being able to participate in the research by, with their consent, sharing their participation with their work or school. Be mindful of what information you share as participants may not have disclosed their health conditions. Have participants approve all information shared with third parties.

What not to do

- Don’t assume the young adults need support unless they ask for it. Make it clear it is available if they require it.
- Don’t use the same communication style for all participants. Adapt your communication and research documents for each ability level.
- Don’t adapt the EMA to each individual so much that you can’t measure feasibility. Keep the core protocol the same for all participants. Make sure you can answer your research question.

Resources



For an indepth step-by-step guide to designing EMA research:

https://www.kuleuven.be/samenwerking/real/real-book

For help selecting what EMA software to use:

"Selecting an Ecological Momentary Assessment Platform: Tutorial for Researchers" (Henry., et al 2024)

Further information about using PPI in research:

https://www.medsci.ox.ac.uk/research/patient-and-public-involvement/section-1-foreword-and-introduction

Good Luck!

Acknowledgements

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References

Davison, J., Maguire, S., McLaughlin, M., & Simms, V. (2022). Involving adolescents with intellectual disability in the adaptation of self-reported subjective well-being measures: participatory research and methodological considerations. Journal of Intellectual Disability Research, 66(7), 628-641.

Henry, L. M., Hansen, E., Chimoff, J., Pokstis, K., Kiderman, M., Naim, R., ... & Brotman, M. A. (2024). Selecting an Ecological Momentary Assessment Platform: Tutorial for Researchers. Journal of Medical Internet Research, 26, e51125.

McNichol, E., & Grimshaw, P. (2014). An innovative toolkit: increasing the role and value of patient and public involvement in the dissemination of research findings. International Practice Development Journal, 4(1).

Myin-Germeys, I., & Kuppens, P. (Eds.). (2022) The open handbook of experience sampling methodology: A step-by-step guide to designing, conducting, and analyzing ESM studies (2nd ed.). Leuven: Center for Research on Experience Sampling and Ambulatory Methods Leuven.

Simons, L., Valentine, A. Z., Falconer, C. J., Groom, M., Daley, D., Craven, M. P., ... & Hollis, C. (2016). Developing mHealth remote monitoring technology for attention deficit hyperactivity disorder: a qualitative study eliciting user priorities and needs. JMIR mHealth and uHealth, 4(1), e5009.

Soyster, P. D., & Fisher, A. J. (2019). Involving stakeholders in the design of ecological momentary assessment research: An example from smoking cessation. PLoS One, 14(5), e0217150.

Wilson, N. J., Mahoney, N., Chen, Y., Marks, A., Buchanan, A., & Cordier, R. (2019). Using experience sampling methods to understand everyday experiences of adults with intellectual disability.

Woolf, T. B., Goheer, A., Holzhauer, K., Martinez, J., Coughlin, J. W., Martin, L., ... & Lehmann, H. (2021). Development of a mobile app for ecological momentary assessment of circadian data: design considerations and usability testing. JMIR Formative Research, 5(7), e26297.

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