Section A: The Research Project

1. **Title of project**

   Walking for Health: Is health improved for adults with Down syndrome following a 12-week progressive walking intervention.

2. **Purpose of study**

   The purpose of this study is to see whether a simple and safe form of exercise such as walking, improves physical, cognitive and biological health in adults with Down syndrome. The findings will help create more inclusive and effective exercise programmes, inform clinical and support services, and guide organisations in promoting lifelong activity for people with Down syndrome.

   Please read the information carefully and contact Miss Ruby Cain if you have any questions (rc993@pgr.aru.ac.uk).

3. **Who is the researcher?** ***(or researchers if more than one person).***

   - Lead Researcher: Miss Ruby Cain. Anglia Ruskin University, Cambridge, UK (rc993@pgr.aru.ac.uk).
   - Main research supervisor: Professor Dan Gordon. Anglia Ruskin University, Cambridge, UK (dan.gordon@aru.ac.uk)
   - Research supervisor: Dr Matt Jewiss. Anglia Ruskin University, Cambridge, UK (matt.jewiss@aru.ac.uk).
   - Researcher supervisor: Dr Don Keiller. Cambridge University, Trinity College, UK (don.keiller@virginmedia.com).

4. **Why have I been asked to participate?**

   You, the parents/caregivers, have been asked to volunteer in the research study as you meet the following criteria:

   Inclusion criteria:

   - A parent/caregiver of a person diagnosed with Down syndrome (Trisomy 21) at birth. The person with Down syndrome must be 18- 65 years old, with no underlying health conditions that will be made worse from participation in physical activity, determined by the completion of an online questionnaire physical activity readiness questionnaire (PARQ).

   You, the parent/caregiver are required to have:

   - Access to a personal laptop/ tablet and mobile device,
   - Can speak and write in simple English,
   - No underlying health conditions that will be made worse from the participation in physical activity, determined by the completion of an online questionnaire (PARQ).
   - Adequate neighbourhood walkability.

5. **How many people will be asked to participate?**

We aim to recruit 42 participants.

6. **Do I (the parent/ caregiver) or the participant have to take part?**

Parents/caregivers and participants are not obligated to take part; you and the participant are free to withdraw from the study at any time and are not required to provide a reason for doing so.

Due to this being a remote led study, you (the parents/caregivers) play an important role in helping the participants follow instructions safely, using the mobile app correctly, and recording the participants perceived effort during the walks. If you, the parent/caregiver, decide to withdraw from the study, ongoing data collection will no longer be possible, so the participant will also be withdrawn.

For any withdrawal requests or queries please contact the lead researcher via email - Miss Ruby Cain, (rc993@pgr.aru.ac.uk).

7. **Has the study got ethical approval?**

The study has been granted ethical approval from the Faculty of Science and Engineering Research Ethics Panel, Anglia Ruskin University, Cambridge, UK.

8. **Legislation relating to this study**

The research project complies with the Data Protection Act (UK, 2018), General Data Protection Regulation (GDPR, 2018), and the Human Tissue Act (HTA, 2004) guidelines for collection of biological material. Further details can be found below relating to how the participant's data will be used and stored.

9. **Source of funding for the research, if applicable**

Agape Charity, Los Angeles, California, United States of America, (https://www.theagapefund.org/about).

10. **What will happen to the results of the study?**

The results of this study will be written up within a report for the development of a thesis and may be written up as a research article and published in a journal and/or presented at (national and/or international) conferences. However, participants' data will always remain anonymous. You, (the parent/ caregiver) and participant, will also have the option to receive a personal copy of the studies results.

11. **Contact for further information**

Lead Researcher: Miss Ruby Cain– rc993@pgr.aru.ac.uk.
Main Supervisor: Professor Dan Gordon– dan.gordon@aru.ac.uk.

Section B: Your Participation in the Research Project

1. **What will you (the parent/ caregiver), and the participant be asked to do?**

Once you have read this information sheet, you and the participant will be asked to each give consent to take part in the study. The participant will be asked to give their consent to take part, then attend an online video call with the lead researcher to check their understanding of the study and the consent that they have provided.

As a part of this form, we will ask for your **home address** (as the parent or caregiver). This is so we can post the participant's epigenetic testing kit, which will be used to collect saliva samples at **weeks 1 and 12.**

You will then both be asked to complete an online **physical activity readiness questionnaire** (PAR-Q). This questionnaire aims to screen for potential medical issues that could be made worse by the participation in regular exercise. If **you or the participant** answer **'YES'** to any of the questions, we will ask that approval is granted from a medical professional before taking part in this study. We will also ask you, (the parent/caregiver) to complete a short online survey that will ask questions about the **local neighbourhood environment.** This survey helps us determine how safe the local outdoor environment is for walking. If the lead researcher feels that the area is not safe, the participant may not be able to take part in the study.

Once these steps are completed, the lead researcher will send you and the participant short, step-by-step videos explaining each stage of the study. These videos are easy to follow and include clear voice-over explanations and visuals. You will also be offered an **optional online meeting** with the lead researcher via Microsoft Teams. During this meeting, the researcher will go through the study information and answer any questions you or the participant may have.

<u>Baseline measurements:</u>

Physical tests:

The first physical test is the **'six-minute-walk-test'.** Participants will be asked to walk as far as they can in a 6-minute time frame. This test will provide insight into the participants **cardio-respiratory fitness**. Participants are permitted to slow down, to stop, and to rest as necessary. The second physical test is the **'talk-test'.** This test will **help determine the participants walking pace** during the main study. Participants will be asked to start walking for 1minute. At the end of each 1minute the participant will be asked to sing the song 'happy birthday'. If the participant can comfortably sing the song the speed of the walk is increased to the next 1minute stage. The test is stopped when the participant can no longer comfortably sing. Participants may find that they have started to jog or even run before this starts to happen, that is fine.

Each physical test should be completed somewhere safe, ideally on flat and even ground. During these tests it is advised that you (the parents/caregivers) walk behind the participants offering encouragement but not setting the pace of their walk. It is encouraged that both you and the participant are wearing comfy clothes with exercise shoes during these tests. Walking data including steps taken, distance (m) and walking speed (s) will be recorded by the mobile app 'Sensor logger' downloaded onto the participants mobile devices. We will provide you with detailed instructions

once admitted into the study, on how to download the app, how to use it and any troubleshooting issues.

Cognitive Tests:

On a separate day, we will ask participants to use their laptop/tablet to complete **three online cognitive tests.** Each test will take between 5-7 minutes to complete and are designed to be fun and interactive. You, (the parent/ caregiver) will be asked to be present during each task to help assist, but not to provide answers. Rests can be taken between each test, however not during a test. Once a test has started the participant cannot stop until the test is over. Participants will have the option to watch a short video demonstration with verbal instructions for each cognitive test to help ensure they understand the tests requirements before beginning.

1. **Colour game:** participants are asked to choose the colour of a word rather than the spelling of the word.

   RED

   The colour of this word is blue, to get this right in the test participants would click the keyboard letter, 'B'. For a red colour, 'R', for a yellow colour, 'Y', for a green colour, 'G'.

2. **Number game:** participants will be asked to press the spacebar on their keyboard for every number that appears on their screen apart from the number 3.

3. **Memory game:** participants will be asked to remember a pattern of flashing blocks. They will be asked to watch the blocks light up and then click them in the order they see them.

Salivary sample: You, (the parents/caregivers) will be sent a saliva test kit to your home address, via tracked recorded delivery. Inside the saliva test kit are instructions, as well as a step-by-step instructional video provided by the lead researcher. Each kit will have a unique code associated to it, so that the participants data remains anonymous.

It is advised that participants do not eat or drink fluids, (excluding water) prior to this test taking place and collect the saliva sample in the morning as soon as they wake up. To complete the test, you (the parent/ caregiver) will be asked to assist the participant, taking the cap of the provided test tube off and screwing on the plastic drool funnel. The participants will then hold the test tube and rest the plastic drool funnel on their lower lip, sitting upright. Participants will drool until the saliva reaches the 2 ml fill line. During this time, participants can take breaks, wipe any excess drool and swallow etc if needed. Once the saliva sample collection is complete you (the parent/ caregiver), will be asked to help the participant remove the plastic drool funnel, which can then be put into a bin. You will then package the sample as directed in the instructions.

<u>Familiarisation:</u>

Participants will complete two familiarisation sessions before the start of the study to practice each test. Each session will be 2 to 3 days apart, to make sure the participant doesn't get tired or unmotivated prior to the start of the study.

Session one: Practice cognitive tests.
Session Two: Practice physical tests and the setting up the app 'sensor logger' onto participants mobile device.

Intervention:

Control group: If the participant is allocated to the control group, **they will not take part in the walking intervention**. Instead, participants will be asked to record their normal daily movement using the "Sensor Logger" app. The app will record steps taken, walking speed (s), and walking distance (m). No other mobile data will be recorded from the app. Participants will be asked to switch the app on in the morning and turn it off at night. This will allow the research team to compare daily movement patterns between the control group and the exercise group. Participants will be asked to continue with their usual daily routine during this time.

Exercise group: If the participant is allocated to the exercise group, they will be asked to take part in a **12-week outdoor walking intervention, for 20<35 minutes, 3 times a week.** The intervention will get progressively harder at weeks 3, 6 and 9, by increasing the duration and intensity of the walks. This will ensure that the participants continue to adapt and don't lose progress throughout the course of the intervention. Participants will be asked, with your continued support, to complete the walks outdoors in a safe environment on flat solid ground, ideally where they completed the pre-intervention physical tests. Participants can choose when to complete their walks throughout the week but must meet the requirements of the study.

Week	Duration (min)	Intensity	Effort
1	20	Light effort (easy to speak without straining for breath).	1-2
3	25	Light-moderate effort (can speak clearly for a sentence or two without needing to pause for breath).	3-4
6	30	Moderate effort (can speak clearly but may need slightly more breath).	4-5
9	35	Moderate to somewhat hard effort (begins to get difficult to speak more than a few words without pausing for breath).	5-6
12	-	End of Test!	-

Monitoring intensity:

To ensure the participant is walking at the correct intensity at each stage of the intervention, you (the parent/ caregiver) will be asked to record **how much effort** the participant put in to completing the activity. This will be done for each physical test and walk included within this study.

A PDF pictural scale ranging from 1- 10 will be provided by the lead researcher, as displayed below. We ask that this scale is shown to participants at the start and end of each physical test and walk. You, (the parent/ caregiver) will ask the participants to point to the number that relates to how strenuous the activity has felt. The number that they point to at the start and end of the test will be recorded on a google form sheet provided by the lead researcher.

How hard do you find the activity?	
0	No effort at all
1	Very Easy
2	Somewhat Easy
3	Moderate
4	Somewhat Hard
5	Hard
6	
7	Very Hard
8	
9	
10	Very Very Hard

The research teams' email addresses are provided throughout this PIS to allow you and the participants the opportunity and time to ask any questions related to the research. Time will be allocated for questions, demonstrations, and further information regarding the testing procedures at any time that you request. Participants are free to withdraw from the study without explanation at any time – please inform Miss Ruby Cain (rc993@pgr.aru.ac.uk) if you wish to withdraw.

2. **In relation to this specific research project, we need to make you and the participant aware of the following:**

We are responsible for the personal data you give to us as a:			
☐	**Data Controller** (We are in sole control over the research)	Who are we:	Miss Ruby Cain Professor Dan Gordon Dr Matt Jewwis Dr Don Keiller On behalf of, Anglia Ruskin University, Cambridge, UK.

3. **I will be asking the participant for the following information:**

Personal Data				Sensitive Personal data	
X	**Name/ Contact details**	X	Image (Photo or video)	X	Racial/ Ethnicity data
X	**Age**	☐	Experiences	☐	Political/ Religious beliefs
X	**Address/ location data**	X	**Biomechanical and functional**	☐	Trade Union membership
☐	Employment & Earnings	☐	[Other]	X	**Genetic/ Biometric data**
☐	ID Numbers (e.g. NHS)	☐	[Other]	X	**Health**
☐	Online identifier	☐	[Other]	☐	Sex life/ orientation

					data

4. What will happen to the participant's data?
Upon the completion of this study, the participant's data will be made anonymous. The anticipated date all data will be anonymised is the 1st of November 2026. Anonymisation of data refers to the process of removing personal identifiers that may lead to a person (i.e., the participant) being identified from that information or combined with other information. The research data will remain in the United Kingdom UK.

The participant's data will be handled as per the Data Protection Act (UK - 2018) and General Data Protection Regulation (GDPR) (2018) guidelines, as found in section 10 below. Anonymous Data will be shared with the research team members only, as outlined above; however, the privacy, rights, and dignity of the participants will be always maintained. Data will be retained for two years after the conclusion of this research project and then deleted.

5. Will the participant be reimbursed for travel expenses?
There will be no travel expenses for this research.

6. Will the participant receive any payment to take part in the research?
There will be no use of incentives to take part in this study.

7. Are there any possible disadvantages or risks to taking part?
Research of this nature has minimal risks; however, every effort has and will be made to minimise these risks and ensure the participant's well-being. Risk assessments have been carried out for all procedures in this study. Possible risks associated with this study include:

1. **Genetic analysis identifies health conditions:** The saliva test may find connections to the participants cellular health and potential health conditions. However, this information is not a medical diagnostic tool and therefore does not represent causality. It does not describe whether the findings of the test directly cause a certain health condition. If the research team believe there are any risks or issues, the participant and you (the parent/ caregiver) will have every right to know and can speak to a medical professional for further information, tests and/or diagnostics. Participants and you (the parent/ caregiver) will have the option of receiving a summary report of the participants epigenetic profile from Muhdohub, who are conducting the saliva test analysis on-our behalf.

2. **Data mishandling:** All data collected will be stored on a custom-made, password-protected Excel file, and stored on a password-protected computer and on a secure, two-factor authentication online repository (i.e. One Drive). The mobile app, 'sensor logger' will only collect walking related data. No other data will be collected from participants mobile devices, (see sensor logger app privacy policy: https://www.tszheichoi.com/sensor-logger-privacy-policy). Walking data collected will remain on the mobile app 'sensor logger' until data collection is complete (i.e. November 2026) and will then be exported to a custom-made Excel file. Participant data will be partially anonymised by research team during data collection with each participant being assigned a participant ID code that only the research team knows. Data will be fully anonymised from Muhdohub/Eurofins. Upon data collection completion, all data will then be made anonymous prior to full data analysis and subsequent thesis/publication write up.

If a participant leaves the intervention during data collection period, only data used up to that point will be analysed if applicable. Participants can ask for their data to be withdrawn up to the point where all data is made anonymous (i.e. completion of November 2026). All data collection and storage used within this study complies with the obligations set under the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, and all other laws relevant to the handling of personal data. The sensor logger data will be used to compare against the results of the epigenetic test and cognitive tests to assess if there is a positive relationship between the walking intervention and the biological age of cells.

3. **Physical injury during walking:** Participants will be asked to walk at a comfortable pace to avoid overexertion, with you (the parents/caregiver) always accompanying them during outdoor walks to ensure their safety. Progression will be reviewed at weeks 3,6 and 9 to avoid sudden intensity increases. This will be done by looking through the participants walking data and reviewing whether they have made gains in the distance or number of steps taken each week. If the participant has not made any improvements or is uncomfortable with increasing the intensity and duration of each walk, then no progression will be made. Participants will be reminded to use appropriate footwear and clothing throughout the intervention.

4. **Falls or tripping while exercising:** Participants will be screened out of completing the study if their neighbourhood walkability is below adequate (determined by a self-administered survey), or if participants do not have access to outdoor leisure facilities necessary for participation (e.g., outdoor athletics track, outdoor football pitch). You (the parents/caregivers) will also always accompany participants, walking behind them during physical tests and the intervention to ensure their safety. All participants are encouraged to stick to safe walking environments with even surfaces and flat ground.

5. **Fatigue or overexertion**: progressive increases in duration and intensity of the walks at weeks 3,6 and 9 will be dependent on the participants' fatigue levels at the end of each walk. Participants will also be encouraged to rest if feeling unwell, with all intervention proceedings closely monitored by the research team.

6. **Emotional discomfort or stress:** participants can withdraw at any time without explaining, with opportunities to ask questions about intervention proceedings at the start and during the study. All physical and cognitive tests are short to complete and are designed to be easy to follow and engaging for participants.

7. **Feeling confused or unsupported**: clear step-by-step videos will be provided to participants and you the parents/caregiver, to cover all parts of the intervention protocol, data collection, and equipment use. Online support will be available 9 am-5 pm on all weekdays via the research team email and online calls via Microsoft Teams.

The participant's agreement to participate in the study does not affect their statutory legal rights. Their participation in this study is voluntary; participants can refuse to take part without giving a reason and may withdraw at any time. Should they decide to withdraw from the study for any reason, please speak to Miss Ruby Cain (Rc993@pgr.aru.ac.uk).

8. What are the likely benefits of taking part?
The main benefit of participating in this research is that participants will engage in regular exercise that has been proven to improve health including cognition, mood, and heart/lung health. We hope that participants enjoy the study and feel physically fitter. Results from the salivary sample will also give a valuable insight into the participant's current health status by revealing how their cells are ageing. Specific methods can then be recommended that might slow that process down.

9. Can the participant withdraw at any time, and how do I do this?
Participants can withdraw from the study at any time without giving a reason. Should participants decide to withdraw from the study following their participation for any reason, please contact the principal investigators via email, Miss Ruby Cain (Rc993@pgr.aru.ac.uk).

10. What will happen to the participant's data?
Our general privacy notice explaining our use of your personal data for research purposes is available here:
https://www.anglia.ac.uk/privacy-and-cookies/research-participants
Please visit this link for information about how long we keep participants data, how we keep their data secure, how they can exercise their rights over their data, and make a complaint over our use of their data.

11. Can the participant withdraw their data from the study?
Participants can withdraw from the study at any point. Upon withdrawal and request, their data collected up to that point will be permanently deleted. However, upon the completion of this study, all data will be made anonymous. The anticipated date all data will be anonymised is the 1st of November 2026, and so, after this point, we will not be able to identify or remove their data.

12. Whether there are any special precautions the participant must take before, during, or after taking part in the study?
Before exercise, you the parent/ caregiver, will be asked to ensure the participant is rested and in a hydrated state, having eaten a well-balanced meal ~2 hours before exercise. All physical activities should take place in safe walking environments with even surfaces and flat ground. You the parents/caregiver will always need to accompany participants, walking behind them during physical tests and the intervention to ensure their safety.

Will I pass on to anyone else what the participant have told me?
The only people who will be able to access the data will be the principal investigator and members of the immediate research team, as outlined above.

13. Summary of research findings
A summary of the research findings will be available and can be provided to participants and you the parent/caregiver, if they or you wish, following the completion of the study. The summary of research findings can be sent to you or the participant via email.

14. Contact details for complaints
If you or the participant have any complaints about the study, we encourage you to speak to the lead experimenter, Miss Ruby Cain, in the first instance. You or the participant can also contact Anglia Ruskin University via email or post for complaints.

Email address: complaints@anglia.ac.uk
Postal address: Office of the Secretary and Clerk, Anglia Ruskin University, Bishop Hall Lane, Chelmsford, Essex, CM1 1SQ.

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