STUDY PROTOCOL

Steps Ahead: optimising physical activity and health in people with cystic fibrosis: Study Protocol for a pilot randomised trial
[version 1; peer review: 1 approved with reservations]

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Abstract

Background: Physical activity (PA) and exercise are widely documented as key components in the management of cystic fibrosis (CF). In recent years there have been significant improvements in telehealth, in particular; fitness tracking, smartphone use and remote monitoring, all of which may have potential to impact on positive health outcomes in people with CF. The objective of this pilot randomised trial is to explore the potential efficacy of a fitness tracker, which is remotely monitored, combined with personalised text message feedback and goal setting, on lung function, aerobic capacity and PA in adults with CF. Secondary endpoints include quality of life, body composition and wellbeing.

Methods: This is a pilot randomised trial which will be conducted at the University Hospital Limerick, Ireland. Participants will be randomised to the intervention or active comparator after their baseline assessment. The 12-week intervention will consist of a fitness tracker (Fitbit Charge 2) which is linked to an online monitoring system (Fitabase) for data collection purposes that enables the physiotherapist to remotely monitor participant data. The CF physiotherapist will set short- and long-term goals with participants and will send one-way text message feedback on Fitbit data and weekly progress. This message will consist of positive reinforcement and re-assess participant goals. The active comparator group will receive a fitness tracker which is also linked to Fitabase; however, no feedback will be provided to participants in this group. Both groups will be re-assessed at...
12 weeks. After this point, both groups will continue with the Fitbit alone for a further 12 weeks. Both groups will be re-assessed at 24 weeks.

**Discussion:** This is a novel concept which utilises modern technology, remote monitoring and personalised feedback to investigate the effect on health outcomes in people with CF.

**Trial registration:** ClinicalTrials.gov NCT03672058 (14/09/2018)

**Keywords**
Physical activity, Randomised trial, Cystic fibrosis, fitness tracker, telehealth

**Competing interests:** No competing interests were disclosed.

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Background

Cystic fibrosis (CF) is a life-limiting, progressive disease which requires lifelong management. The prevalence of CF is 7 per 100,000 in the European Union, with Ireland reporting the highest incidence of CF in the world (Farrell, 2008). CF is a multisystem disease, primarily affecting the respiratory system which leads to recurrent pulmonary infections with retained secretions, airway obstruction and hyperinflation (Chmiel & Davis, 2003). There is significant burden associated with CF for the individual with CF, their family and wider society. Issues related to treatment adherence (Sawicki et al., 2009) and psychological wellbeing (Quittner et al., 2016) are frequently reported in the literature, especially in adults that are balancing family, work and education, as well as managing their chronic disease (Boyle, 2003).

Exercise and physical activity (PA) are widely documented in consensus statements as key principles in the management of CF (Castellani et al., 2018). Higher levels of exercise amongst people with CF (PWCF) are associated with improved sputum clearance (Dwyer et al., 2009), muscle strength (Burtin et al., 2013), increased survival (Nixon et al., 1992) and improved quality of life (Sawyer et al., 2004). In addition to this, a higher level of PA has been linked to greater bone mineral density (Wilkes et al., 2009), greater exercise capacity (Hebestreit et al., 2010) and a slower rate of decline in lung function in PWCF (Schneiderman et al., 2014). As a result, the optimisation of PA among PWCF is important, however, a Cochrane review found that there was a lack of evidence regarding strategies to promote PA in this population and consideration should be given towards telemedicine applications and health coaching (Cox et al., 2013b).

The evolution of telehealth in CF management is significant in recent years. Previous studies have investigated the effect of telehealth on monitoring health status (Grzincich et al., 2010), detecting exacerbations (Lechtzin et al., 2017; Wood et al., 2017), assessing exercise capacity (Cox et al., 2013a) and providing outpatient appointments (Wood et al., 2017). Telehealth is well accepted by PWCF (Cox et al., 2012). While home monitoring via telehealth seems to be a progressing area of CF management, to date, no studies have evaluated the effect of telehealth on PA and health outcomes in PWCF. Smartphones and fitness trackers may assist CF physiotherapists as they can access PA data remotely (Tagliente et al., 2016). Remote monitoring and home-based PA interventions in PWCF are advantageous for several reasons. It enables the intervention to be easily implemented, participants’ personal preferences can be considered, it is more accessible to all participants and it can involve family/friends (Hebestreit et al., 2010). As a result, these benefits may increase adherence to the intervention. Fitness trackers and text message feedback has had positive health outcomes amongst other study populations (Cadmus-Bertram et al., 2015; Cook et al., 2013; Vaes et al., 2013), however limited research has been conducted among PWCF to date.

In addition to telehealth, goal setting and reviewing goals regularly should be considered to support patients with chronic illness (Coleman & Newton, 2005). In order for goals to be achieved, feedback should be provided that reveals progress in relation to the goal (Locke & Latham, 2002). Furthermore, setting specific goals should offer a plan to break PA goals into more practical, manageable steps (Shilts et al., 2004) which should increase self-efficacy and hence promote continued regular PA levels (Bandura, 2004). The Irish national framework for self-management includes goal setting and action planning in chronic disease management (Chronic Conditions Working Group, 2017). However, goal setting to increase PA in PWCF is poorly investigated.

This randomised pilot trial aims to explore the impact of a fitness tracker, text message personalised feedback and goal setting on PA and health outcomes in PWCF. The current protocol serves to:

- Describe the methodology that will be implemented to evaluate a 12-week personalised remote monitoring, text message feedback and goal setting amongst PWCF attending University Hospital Limerick
- Describe the health outcomes in PWCF that will be evaluated in the trial including PA levels, lung function, aerobic capacity and quality of life
- Describe the nested process evaluation through the conduct of semi structured interviews amongst PWCF and healthcare practitioners regarding the implementation, delivery and acceptability of the intervention.

Methods

Study design

This study represents a single centre randomised pilot trial which will compare the potential efficacy of a fitness tracker with personalised text message feedback and goal setting to a fitness tracker alone in PWCF. The CONSORT standardised reporting guidelines will be followed to ensure the standardised conduct and reporting of the research (Schulz et al., 2010). This protocol was registered on ClinicalTrials.gov (NCT03672058) on 14th September 2018 and prepared in accordance with the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (see Figure 1 and Reporting guidelines).

Setting

The study will take place in the Adult CF Unit, University Hospital Limerick, Ireland. Baseline and follow-up assessments will take place via outpatient appointments. Due to the nature of the intervention, blinding of participants is not possible.

Ethical approval

Ethical Approval was obtained from the University Hospital Limerick Research Ethics Committee (Approval number 054/18).

Population and recruitment

Recruitment strategy. Participants deemed eligible for inclusion to the study based on the inclusion/exclusion criteria will be approached by the study gatekeeper (CF Physiotherapist – LC)
and provided with an outline of the study during their routine clinic appointment. Participants will be provided with an information leaflet and will be offered an opportunity to ask questions about participation in the study. Prospective participants will then be asked to sign a consent form. Consent and mechanisms relating to data controlling and processing will be compliant with the EU General Data Protection Regulation 2016/679 and in compliance with the Data Protection Act 2018 [(Section 36(2)) (Health Research) Regulations 2018].

Sample size
As this is the first study of its kind a sample size cannot be determined. However, based on inclusion/exclusion criteria and the number of participants eligible for this study at University Hospital Limerick, it is intended to recruit up to 50 participants.

Inclusion criteria
- Age ≥ 18 years
- Confirmed diagnosis of CF
- Clinically stable patients with CF attending University Hospital Limerick, determined by those who are not experiencing a pulmonary exacerbation. For the purpose of this study pulmonary exacerbation will be defined as acute or subacute worsening of respiratory symptoms which warrant change in treatment (i.e., new oral or

**Figure 1. Study Schedule.**
intravenous antibiotics), as per previous research (Savi et al., 2015).

- Access to a smartphone/tablet to access and ability to upload to Fitbit Application
- Capacity and willingness to give explicit informed consent

Exclusion criteria
- FEV$_1$ < 25%
- Patients on the waiting list for lung transplantation and those who have undergone lung transplantation.
- Patients with an exacerbation in the four weeks prior to the study. Patients can undergo testing once they are finished their antibiotics and deemed clinically stable by the Respiratory Consultant (BC).
- Patients dependent on supplemental oxygen for exercise.
- Pregnancy
- Participation in another clinical trial up to 4 weeks prior to the first baseline visit

Randomisation
Should participants explicitly consent to participate in the study, they will undergo baseline testing. To minimise the possibility of selection bias, a researcher independent of the recruitment process (MC) will complete the first random allocation using a sealed opaque envelope. Following this a minimisation randomisation procedure will be completed based on lung function, where FEV$_1$ of <70% predicted lung function will be classified as having mild lung disease. While those with an FEV$_1$ of 30–50% predicted lung function will be classified as having moderate lung disease, with <30% indicating severe lung disease. Allocation will be revealed after recruitment and baseline assessments have occurred. Participants will then either receive the intervention (Fitbit with text messaging feedback and goal setting) or the active comparator (Fitbit only).

Experimental and active comparator intervention

Intervention
If the participant is allocated to the intervention, they will be provided with a fitness tracker, educated on how to use it and this will also be linked to “Fitbase” for data collection purposes. However, no feedback will be provided to the participants on their PA levels.

Follow Up
At week 12 both groups will have outcome measures re-assessed. Both groups will continue with the fitness tracker only for the following 12 weeks. At the end of the 24 weeks participants will have all outcome measures repeated.

Subsequently, a qualitative assessment will be conducted through semi structured individual interviews to determine participants’ satisfaction and feedback on the intervention and their suggestions going forward. The interview guide is available as extended data to this manuscript (Curran, 2020). These interviews will be completed by a CF Physiotherapist involved in the study (LK) using a digital voice recorder and will be transcribed verbatim. The transcribed texts will be coded independently by two investigators who will develop code books. These will be compared and agreed upon. Data will be analysed using NVIVO V.11 Plus (QSR International Pty Ltd) and using the six steps for thematic analysis, in order to highlight the central themes to this study (Braun & Clarke, 2006).

Exacerbations
If the participant has an exacerbation of CF during the study period, their involvement in the study will be paused, and re-started 1 month later.

Instrumentation/outcome measures
A range of outcome measures will be employed to identify the potential impact of this study on health outcomes in PWCF. Each of these outcomes will be assessed at baseline, at 12 weeks and 24 weeks.

Primary
Cardiopulmonary exercise testing
The reference standard exercise test is an incremental cardiopulmonary exercise test (CPET), utilising a ramp protocol. This will be conducted using the Medisoft Ergocard Professional CPET equipment and analysed by ExpAir, the Medisoft software. Maximal exercise testing is an independent predictor of mortality in CF (Nixon et al., 1992). Breath-by-breath ventilatory gas analysis allows the accurate measurement of maximal oxygen uptake (VO$_{2\ max}$) – the gold standard measure of exercise capacity (Urquhart, 2011).

Spirometry
Pulmonary function testing spirometry will be performed according to American Thoracic Society (ATS) standard techniques (Miller et al., 2005) using the Carefusion Microlab spiroimeter. Values will be expressed as a percentage of the predicted value for height, sex and age for adults (Hankinson et al., 1999). Forced expiratory volume in one second (FEV$_1$) will be used to classify the severity of CF lung disease for each participant.

Secondary
Fitbit step count data
The Fitbit Charge 2 will be used to record step count during this study with data uploaded to Fitbase. The Fitbit Charge 2
is a valid and reliable measure to assess step count in PWCF (Curran et al., 2020).

International Physical Activity Questionnaire (IPAQ)
The IPAQ is a self-reported measure of PA and relies on user recall over the previous seven days. This tool was developed to assess PA levels using a questionnaire, has very good repeatability and is as reliable as other measures for self-reported PA (Craig et al., 2003). This nine-item questionnaire relies on participant recall and records PA at four levels: vigorous (e.g. aerobics), moderate (e.g. leisure cycling), walking and sitting.

Hand dynamometry
Grip strength will be recorded as a measure of overall physical function, independent of lower limb strength. This will be conducted using a Jamar Hydraulic Hand Dynamometer. Test – retest reliability has been proven in respiratory patients (Dowman et al., 2016).

Bioelectrical Impedance Analysis (BIA)
BIA is an easily available, quick method to assess body composition. A low voltage current will be passed through the body, whereby impedance (tissue resistance and reactance) is measured. This will be conducted using the Seca 515 Medical Body Composition Analyser. BIA will be performed with the participant standing barefoot on the instrument platform as per manufacturers guidelines (Seca, Birmingham, United Kingdom). The device has an integrated scale and uses four pairs of electrodes of stainless steel that are positioned at each hand and foot, through which the current enters the limbs.

CF Quality of Life Questionnaire Revised (CFQR)
The CFQR questionnaire is a fully validated disease specific measure consisting of 52 items across nine domains of functioning which have been identified by, and are of importance to, adolescents and adults with cystic fibrosis. This questionnaire is valid, sensitive and has strong test-retest reliability (Gee et al., 2000). The minimum clinically important difference for the CFQR – respiratory score is 4 points (Quittner et al., 2009).

Pittsburgh Sleep Quality Index (PSQI)
The PSQI is a self-rated questionnaire used to measure the quality and patterns of sleep in adults. It differentiates “poor” from “good” sleep quality by measuring seven areas (components): subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medications, and daytime dysfunction over the last month. The PSQI is effective in assessing sleep quality in adults with CF (Milross et al., 2002).

The University of California San Diego (UCSD) Shortness of Breath Questionnaire
This questionnaire assesses dyspnoea associated with activities of daily living (ADLs). There are 24 items on this questionnaire. Each item is assessed on a 6-point scale (0 = “not at all” to 5 = “maximal or unable to do because of breathlessness”). Scores range from 0 to 120 with higher scores indicating activities of daily living are extremely limited by shortness of breath. It has been validated to assess dyspnoea over time in respiratory patients (Swigris et al., 2012).

Awescore
This questionnaire assesses state of wellness to assist in providing best health care (Button et al., 2014). There are ten questions, which are scored from 0–10. 10 reflects most well state of being possible while zero reflects least well state. Scores range from 0–100 with higher scores indicating good state of wellness. This is a reliable tool for measurement of multidimensional wellness in adults with CF that is appealing to patients (Button et al., 2014).

Data collection & management
Outcome assessment will be conducted by qualified physiotherapists in the Adult CF Unit. Assessors cannot be blinded as the intervention involves the CF physiotherapists for the delivery of weekly text messages, who will also be assisting with repeating objective outcome measures. However, all self-report measures will be completed by the participants and these subjective assessments will be analysed by a research assistant (RA) (AJ) who is blinded to group allocation.

Each participant in the study will be assigned a numerical identifier code. Aggregate data will be anonymised. Paper copies of all measures will be identifiable only by the identifier code. All data will be stored in locked filing cabinets in locked offices in the Adult CF Unit at University Hospital Limerick. All identifying paper data (e.g. signed consent forms and forms listing participant codes) will be stored in a separate locked filing cabinet to all other anonymised data and will be accessible only to the research team. All interviews will be coded and entered to a study data file. These computer files will be stored on the hard drive of a password protected desktop computer by the study lead investigator (MC). All audio and electronic data will be stored on encrypted hard drives.

Data analysis
Appropriate descriptive statistics will be used to describe the baseline characteristics of study participants. These will include proportions, percentages, ranges, means and standard deviations and medians and interquartile ranges (where data are not normally distributed). Data will be assessed for normality. Parametric tests will be used to compare differences across groups where data are normally distributed, and the non-parametric equivalent will be applied in cases where data are not normally distributed. A p-value <0.05 will be considered significant. In case of missing values, a multiple imputation method will be used to handle the missing data. All data will be analysed using SPSS.

Dissemination of information
The results of this study will be disseminated via peer-reviewed publications and conference presentations.
Study status
Recruitment began in January 2019. It is anticipated this will be completed by June 2020.

Discussion
This is the first study to assess the potential efficacy of a fitness tracker with personalised feedback and goal setting on key clinical outcomes in PWCF. Previous studies have investigated telehealth in CF (Cox et al., 2012) and while there is insufficient evidence to draw firm conclusions as of yet, it is worth investigating the effectiveness of telehealth on PA in PWCF.

The use of fitness trackers with remote monitoring is a novel concept in CF. Previous literature has demonstrated that a partially supervised programme in CF can improve health outcomes and is easily implemented (Hebestreit et al., 2010). Other partially supervised interventions have investigated the effect of providing personalised text message feedback on PA levels which has enhanced adherence to home based programmes in other populations (Blaauwbroek et al., 2009; Strath et al., 2011).

The broad range of outcomes assessed in this study will facilitate a comprehensive review on the impact of this research on participants with CF, both subjectively and objectively. A strength of this study is the use of the Fitbit Charge 2 which will allow participants to update their PA levels through the Fitbit App which will enable the assessors to review data remotely and this will also provide feedback on compliance to the intervention.

There is no true control group in this study for a couple of reasons. Firstly, the primary aim of this study was to determine if a partially supervised programme would be effective in improving PA and health, and it is unknown if any of these key outcomes could be improved with the provision of a Fitbit alone. Therefore, it was deemed more appropriate to compare the intervention with the Fitbit alone rather than a true control group. Secondly, the CF Physiotherapists felt that this would be a limitation to recruitment if only one group received the Fitbit.

Gene modifiers and potentiators may be a confounder in this study. This will be monitored throughout the study duration and will be controlled for during statistical analysis, if necessary.

The results of this study may provide valuable insights into the development of a larger definitive trial exploring the use of telehealth for optimising physical activity and health outcomes in PWCF.

Ethics approval and consent to participate
The study received ethical approval from the University Hospital Limerick Research Ethics Committee (Ref: 054/18). Written informed consent will be obtained from all study participants.

Data availability
Underlying data
No data are associated with this article

Extended data

This project contains the following extended data:

- Participant Consent Form
- Participant Information leaflet
- Interview Guide

Reporting guidelines

Data are available under the terms of the Creative Commons Zero “No rights reserved” data waiver (CC0 1.0 Public domain dedication).

References

Bandura A. Health promotion by social cognitive means. Health Educ Behav. 2004; 31(2): 143–164. Published Abstract | Publisher Full Text
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Thank you for asking me to review this interesting and very topical protocol.

The authors have made a very good effort at identifying the need for undertaking this study (which is even more relevant given the current circumstances around the world) for PWCF. As the authors correctly say there is an ever increasing research base investigating telehealth for individuals with long term conditions such as CF so this is a pertinent and relevant study protocol.

Below are some specific section comments:

Title:
The title is a little confusing as health is all encompassing and can include many factors from physical to mental health. Physical activity itself also includes exercise so I think that the authors perhaps need to consider making the title a little more specific to the study aims and objectives. For example is exercise going to be assessed separately to physical activity from the steps data using perhaps HR data from the FitBits? In the abstract introduction quality and wellbeing have been used as secondary ‘endpoints’ - is this what the authors are referring to when they say health in the title. Perhaps the title should be more specific to reflect this? Also is the aim of the study not more focussed on investigating the ability of telehealth to impact on health behaviours in PWCF? There is no mention of telehealth or technology in the title - perhaps this should be considered?

Abstract:
The abstract is relatively clear however consistency with the title as suggested above is needed in terms of the aims of the study.
The manufacturer details are needed for the Fitbit and the Fitabase to ensure reproducibility.
What does the online monitoring system actually do - there are limited details pertaining to this? What type of data is collected and how often and therefore what type of information is available to the healthcare professional.
I think the authors need to be clear about what the text messages will include - is it only positive reinforcement plus changes to targets based on the weekly step counts etc (how will this be progressed?)
Is a standardised method going to be used for all participants? References perhaps needed for this. Or will it also include ‘feedback’? What will the ‘feedback’ include?

Is there a need for a wash-in period (to allow for the novelty effect) at the beginning of the study and/or a washout period between the 12 week time period to allow for the positive or negative impact of familiarisation of using a fitness tracker?

A point of note: wearable technology is a more appropriate term rather than fitness tracker.

**Background:**
There is a lack of data to support the statements being made throughout this section e.g. ‘higher levels of exercise’ what do the authors mean by higher and using what outcome measures?

More specific detail is required in terms of the evidence base being used to support the aims, objectives and methodology of this protocol under the 4 sub sections - CF, PA, telehealth and goal setting.

A clear definition of physical activity is needed. Exercise is a sub section of physical activity and it is not clear if an specific ‘exercise’ intervention is planned via the SMS ‘feedback’ which should be outlined.

In addition in the background reference to the need for an assessment of delivery and acceptability is made but this has not been mentioned in the abstract or introduction.

**Methods:**
What do the authors mean by efficacy? Is engagement with the technology enough for the study to be deemed efficacious? Will engagement with the technology be recorded?

Will the outcome measures be measured during routine outpatient appointments - or will additional appointments need to be made? What will the additional burden (physical and time) be for the participants? Has there been any PPI used in the planning of this study to take this into account?

Exclusion criteria - why have individuals with a FEV1<25% been excluded?

The term PWCF who are pregnant rather than pregnancy should be used.

No mention of ‘usual care’ has been given and would be useful for the reader to understand with respect to physical activity advice and interventions that the participants normally receive.

Randomisation: the lung function categories are confusing - <70% mild - should this not be 70% and above? 30-50% moderate - what about those with 51-69%.....?

Intervention - more detail is needed to clearly explain and outline all of the details pertaining to the initial information - how will this be provided - verbal or written form? What will it include? Etc.

How will baseline physical activity be measured? Using the Fitbits provided or another accelerometer? How long will this be measured for? Specific details are needed here - number of hours and on which days - weekdays and/or weekends etc.

Goal setting intervention - what strategies and approach will be used for this? Will a specific standardised format be used for each participant? How many goals will be used? Will this be standardised?

As previously mentioned are wash-in and washout periods needed for data collection? Would a
randomised crossover study design be more useful to account for this?

**Outcome measures:**

**Primary:** In the abstract PA is included as a primary endpoint but listed as a secondary outcome here.

Is CPET an appropriate primary outcome measure - an exercise intervention has not been included or described in this protocol. Is the aim for fitness to be impacted or PA only? This needs to be clarified. Has the well validated supramaximal verification CPET protocol for PWCF been considered as an option? More details are required regarding the 'ramp protocol' that has been referred to and a reference added. What outcomes will be used from the CPET - VO2 max only or will others be considered e.g. VE/VO2, RER as well as standard CPET outcomes in terms of duration, load etc. More details are needed.

Is FEV1 only going to be used as a classification measure? If this is the case then it is not a primary outcome measure but purely a method of categorising the participants rather than a measure of change or a measure of the impact of the technology.

Are other PFTs measures going to be considered?

**Secondary**

More detail regarding the step count data collection needed. How frequently will data be collected? How will this be analysed - how many timepoints? Will all 7 days be used or only those with a pre-specified number of hours data? Etc.

More detail is needed regarding the protocols for each of the outcome measures e.g. hand dynamometry - will it be a best of three measure, what unit of measurement will be used, will a standardised protocol be used - what does this include?

Will the participants complete the questionnaires independently or in the presence of a study team member?

Why is sleep being used as an outcome measure? What is the relevance or need for this? Its not clear. This perhaps comes back to my comment regarding a need for a clear definition from the outset for 'physical activity and health'.

There are a lot of outcome measures - again the burden to the participant needs to be considered? Has participant fatigue been considered? Are all measures necessary to answer the research question?

Data analysis: limited statistical analysis plans have been provided. Further details are needed and some reference to intention to treat analysis, missing data and drop outs is required. In addition it would be useful to have an idea as to the possible options for data display.

**Discussion:**

The discussion is quite limited and a number of broad generalised statements have been made which require further detail and explanation to fully convince the reader of the rationale and need for this study.

A clear and evidence based discussion as to the validity and reliability of the chosen wearable technology is also needed.

A brief reference to the fact that gene therapy will be monitored during the study has been made - this is a very important point and needs to be considered carefully. A clear outline of what 'other' data will be
monitored during the study is also needed - e.g. hospital admission, clinical appointments, colonisation status etc.

**Is the rationale for, and objectives of, the study clearly described?**
Partly

**Is the study design appropriate for the research question?**
Partly

**Are sufficient details of the methods provided to allow replication by others?**
No

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Cystic Fibrosis, Physical activity, exercise, health technology.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.