Project summary

Study title	Adaptation of the Welsh National Exercise Referral Scheme (NERS) to virtual delivery: Evaluation of impact and opportunities
Planned study period	13 months (January 2021 to June 2022)
Study design	Mixed methods
Research aim/s	To examine the impact of using face-to-face and/or virtual modes of delivery for NERS in order to support future decision making about programme implementation
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Funder	National Institute for Health Research (NIHR) Award ID: NIHR131573; Project ID: NIHR134153
Protocol version number and date	V1.2

Contents

1 Title and additional identifiers

1.1 Full title of the study
Adaptation of the Welsh National Exercise Referral Scheme (NERS) to virtual delivery: Evaluation of impact and opportunities

1.2 Short title of the study
NERS: Evaluation of adaptation to virtual delivery

1.3 Registry
[add reference and date once registered]

1.4 Funding
Funding is provided by the National Institute for Health Research (NIHR) PHIRST initiative (Public Health Research funding stream).

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1.5 Research team

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2 Background information

2.1 Overview of the intervention to be evaluated and contextual information

The National Exercise Referral Scheme (NERS) is a Welsh Government funded scheme which is centrally managed by the Welsh Local Government Association (WLGA) working in partnership with Public Health Wales (PHW) and has been in operation since July 2007. The Scheme operates in all 22 Local Authority areas of Wales to standardise exercise referral opportunities across all Local Authorities and Local Health Boards. The Scheme is an evidence-based health intervention that incorporates physical activity sessions and behaviour change content. It supports service users to change and maintain physical activity behaviour to improve their physical and mental health and wellbeing.

The aim of NERS is to reduce inequalities in ill health by providing access to tailored and supervised physical activity. The target population includes those aged 16 years and over, who are sedentary and/or deconditioned through inactivity, and are at risk of, or currently experiencing, a long-term health condition. Individuals are first referred to NERS by their GP or allied health professional (e.g. physiotherapist, dietician). Following referral, individuals receive a letter from their local NERS coordinator inviting them to book a consultation session. At this consultation, their allocated Exercise Referral Professional (ERP) introduces them to the programme and uses Motivational Interviewing to assist them in developing short, medium, and long-term goals. Assessments of physical activity, health and wellbeing are also made at this time. A 16-week programme of exercises sessions is then initiated. These sessions are designed to be fun, rewarding and easily incorporated into everyday life. In the first four weeks, users are closely supervised by their ERP to ensure that they are engaging with the programme and performing the activities safely. Once this is established, users are afforded more independence. At 16 weeks, service users are assessed on the same measures once again. At this point, most service users are signposted to exit routes so that they can continue to embed exercise into their daily lives. Service users on specialist pathways for specific conditions/risk factors may however be offered one further 16-week programme of sessions if this is deemed beneficial. Service users receive a further repeated assessment at 52 weeks to measure long-term outcomes.

2.2 The problem being addressed and why this research is needed now

Evidence on the uptake, engagement, retention, effectiveness and costs of exercise referral schemes is equivocal. There are a range of barriers that have the potential to impact upon these measures. In March 2020, the NERS programme had to adapt from face-to-face to virtual delivery in order to continue to support users on the programme during the Covid-19 pandemic. Using routinely collected monitoring and evaluation data, supplemented by additional primary research, this change provides an opportunity to examine the effect of mode of delivery on programme process and outcome measures. Mode of delivery has the potential to act as both a barrier and a facilitator of programme uptake, engagement and retention, and to have either a beneficial or deleterious effect on outcome and costs. Importantly, effects may be moderated by demographic and health/wellbeing related factors, such that for some people it confers a benefit, and for others a disadvantage. This research is timely. The number of referrals to NERS is growing annually such that demand is beginning to outstrip capacity. Offering all or part of the scheme in a virtual format has the potential to increase capacity and therefore the number of people who can be supported. This research aims to explore this potential and to tease apart for which groups it is and is not appropriate, thus enabling scheme commissioners/managers to make evidence-based decisions about the future ways in which NERS could or should be delivered.

2.3 Review of existing evidence

Exercise referral schemes have shown mixed evidence in their ability to improve physical activity and wider wellbeing outcomes (e.g. Pavey et al., 2011), with one review suggesting that 17 inactive adults would need to be referred for one to become moderately active (Williams et al., 2007). Across several systematic reviews, both the definitions and level of uptake (ranging from 35-81%) and attendance (ranging from 12-49%) showed considerable variation (Shore et al. 2019). In normal delivery circumstances, facilitators to adhering to these schemes include social support and personalised sessions, and barriers include negative perceptions about gym atmosphere and equipment, and location and cost factors (Morgan et al., 2016). There have also been issues with differential uptake based on factors such as living with mental health challenges and/or in an area of deprivation (Morgan et al., 2020). However, recent evidence from Australia regarding their accredited exercise physiologist (AEPs) services showed that service users living in areas of greater disadvantage utilised these government-subsidised services at a higher rate and paid lower fees than those living in less disadvantaged areas (Craike et al. 2018).

3 Study Information

3.1 Aim

To examine the impact of using face-to-face and/or virtual modes of delivery for NERS in order to support future decision making about programme implementation.

3.2 Research questions

1	What are stakeholder views and experiences of NERS when delivered in face-to-face and/or virtual formats, how do they compare, and what are the implications for programme uptake, engagement, and delivery?
2	Does offering a version of NERS in which some elements may be delivered virtually affect service-user uptake?
3	Does implementing different versions of NERS, in which either some or all elements are delivered virtually affect service-user engagement?
4	Does implementing different versions of NERS, in which either some or all elements are delivered virtually, affect service user retention?
5	Does implementing different versions of NERS, in which either some or all elements are delivered virtually, affect health and wellbeing outcomes?
6	What are the expected resources and corresponding costs (including impact on service user out-of-pocket expenses) of delivering core parts of the NERS programme, and do they differ for face-to-face and virtual delivery?

4 Study design and methods

Table 1 below refers to three different types of programme used to deliver NERS to date that will be referred to in this protocol.

Table 1. Types of NERS programme delivery

Name of programme type	**Description of programme type**
Standard	This is the standard NERS programme in operation from inception (in 2007) through to March 2020 (when the Covid-19 pandemic forced a change in delivery mode). Core elements of this programme (consultation/first assessment, 16-week assessment, and exercise sessions) were by default delivered face-to-face and on-site (e.g. at leisure centre). In some circumstances, for example where travel to the site was difficult, users could opt for one of their two weekly exercise sessions to be supported via a home programme set by their ERP (written home programme of exercise sessions)
Virtual	This is the first adaptation of the NERS programme in light of the Covid-19 pandemic in operation from March 2020 (until replaced by the modified version). No new referrals were taken on during this time. To receive the virtual programme, all service users had to have had their initial consultation/assessment and to have been on the standard programme for a minimum of 4 weeks. Users were supported through virtual delivery of exercise sessions (live and/or pre-recorded). As an alternative, users who didn't want virtual delivery could choose to be supported through a home programme, supplemented with telephone calls. Sixteen-week assessments

	were conducted via video call or telephone.
Modified	This is the second adaptation of NERS in light of the Covid-19 pandemic and in operation from May 2021 (timing of initiation varied by local authority). New referrals were accepted. Service users (on the standard programme) who declined offer of the virtual programme were also accepted directly back on to the programme (providing no change in health condition otherwise a new referral was required). Exercise sessions were either delivered face-to-face (indoor or outdoor) or remotely (live virtual session by default but additionally by home programme if necessitated by the circumstances of the service user). The consultation/first assessment and the 16-week assessment were delivered face-to-face (indoor) or virtually (video call). How these activities were to be delivered was determined for each service user based on a combination of their clinical vulnerability and the Welsh national/local Covid-19 alert levels at that time (see appendix A for criteria).

4.1 Study design overview

This is a mixed methods study. Research questions will be answered using existing, routinely collected monitoring and evaluation data collected by the NERS programme, and additional qualitative data. The work will be organised across four workstreams as follows:

- Workstream 1: Qualitative process evaluation with service providers
- Workstream 2: Qualitative process evaluation with service users
- Workstream 3: Quantitative outcome and health economic analysis
- Workstream 4: Data synthesis and dissemination

Further detail on each of these workstreams is provided in sections 4.3-4.6 below.

4.2 Co-production and PPI

4.2.1 Co-production

Co-production is a central tenet of the Central PHIRST initiative and our evaluation plans. This evaluation will be co-produced by the Central PHIRST team with Public Health Wales, the Welsh Local Government Association, and local partners and stakeholders, including service users, all working together to plan, design, deliver, and disseminate the evaluation. We will routinely communicate and consult with these partner organisations and stakeholders, and in addition present proposals and updates to our Independent Core Advisory Board (composed of relevant stakeholders in the field of public health and evaluations, which includes academics, third sector, governmental and public expertise) and our Wales NERS specific Advisory Group (similarly composed of key stakeholders but with membership more closely reflecting the subject and area of the evaluation). The feedback they provide will shape key decisions within the research process including design, ethics and dissemination. Further details on our PHIRST advisory and consultative groups can be found in section 6.2 below.

4.2.2 Patient and public involvement

The University of Hertfordshire is committed to involving the public in all stages of its research and has an existing Public Involvement in Research group (PIRg) comprised of members of the

public, service users and carers. PPI (patient and public involvement) involvement is key to the Central PHIRST and will be integral at all stages. All PPI activities will be co-ordinated by the PPI co-investigator (Amander Wellings), the academic PPI co-investigator Professor Julia Jones and members of the PHIRST team.

For this evaluation, PPI will be embedded in two ways through:

1. Central PHIRST Public Involvement in Research Group (PIRg): this group is hosted by the University of Hertfordshire and will collaborate with the research team across all projects; and
2. NERS Public Voice Group: this will take the form of consultation with service users across Wales, who have lived experience of participating in the NERS or of being referred to NERS and declining to participate

The PHIRST PIRg will provide public, service user and carer perspectives to all the public health evaluation projects conducted by the team. The nine members of the PIRg meet monthly to discuss key aspects of Central PHIRST evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and in between meetings, will work closely with the PHIRST to co-produce the evaluation.

The NERS Public Voice Group has been assembled specifically for this project. Service users with lived experience of NERS, or of being referred and declining to participate, have been identified and will be asked to advise on, and assist with, key aspects of our methodology, data collection, and implementation/impact work. These service users will attend four group consultations during 2021/22, which coincide with key points in project. They will be asked to provide a service user perspective on how we conduct the evaluation, help us to make sense of the findings and to co-produce dissemination that is accessible to service users, carers and members of the public.

Both the PHIRST PIRg and the local NERS Public Voice group will be involved in the dissemination of the projects and its impact strategy.

4.3 Workstream 1: Qualitative process evaluation with service providers

Research question

1	What are stakeholder* views and experiences of NERS when delivered in face-to-face and/or virtual formats, how do they compare, and what are the implications for programme uptake, engagement, and delivery? *stakeholders include those invited, those attending and those delivering NERS

Design
Qualitative focus groups

Primary outcome
Not applicable (qualitative research)

Piloting
Ahead of their use, we will pilot the focus group method and schedule with NERS coordinators (see section 5 'Capacity Building' below for further details on this group)

Recruitment and sampling
Maximum variation sampling will be used to achieve a sample which represents (within pragmatic and total sample size constraints) Exercise Referral Professionals (ERPs) from across the 22 Welsh local authority areas. The NERS programme manager will collect initial expressions of interest from NERS ERPs and consent to share contact details with the research team. These will be provided to the team along with data on local authority area. The research team will use this data to purposively select individuals in order to create balance across the sample as described above. Potential participants will be emailed consecutively with a link to our secure survey software REDCap (residing on the UH server). This process will continue until sampling quotas for our criteria are filled. REDCap will be used to present participant information, collect informed consent and basic demographic information, and to book participants on to the scheduled focus groups.
Inclusion/exclusion criteria: all ERPs employed by the NERS programme, who have provided consent for their contact details to be shared with the PHIRST team, will be eligible to participate.

Setting
All data will be collected remotely (i.e. using the video conferencing software Zoom).

Procedure
We will conduct three focus groups with five to eight participants per group, providing us with a total sample size of between 15-25 participants. Focus groups will take place online, facilitated and moderated by members of the research team. We will be training two service providers (NERS coordinators) to support us in this process as part of our capacity building activities (see section 5 below for further details). To participate in a focus group, participants will need to have individual access to the video-conferencing software Zoom (either from their own device or from a device provided by the service-provider organisation—in the latter case, they will also be provided with a private space to participate in the focus group). We will assist participants in downloading this software if necessary. Participants may choose to participate using audio only, or video plus audio. Focus groups are expected to last approximately one hour. Audio recordings will be fully transcribed prior to analysis.

Analysis
The focus group transcripts will be analysed using Framework Analysis (Gale et al., 2013) with an initial inductive coding approach. NERS coordinators that we are supporting (see section 5 'Capacity Building' below) will contribute to this process. The themes and subthemes will then be mapped deductively in accordance with the socio-ecological approach (Sallis, 2015). The SEM is a theoretical model which focuses on the social and physical contexts of behaviour during critical evaluation of interventions.

4.4 Workstream 2: Qualitative process evaluation with service users

Research questions

1	What are stakeholder* views and experiences of NERS when delivered in face-to-face and/or virtual formats, how do they compare, and what are the implications for programme uptake, engagement, and delivery? *stakeholders include those invited, those attending and those delivering NERS

Design
Qualitative interviews

Primary Outcome
Not applicable (qualitative research)

Piloting
Ahead of their use, we will pilot the interview method and schedule with the NERS Public Voice group.

Recruitment and sampling:
We will aim to recruit 15-20 participants in total. Maximum variation sampling will be used to achieve a sample which represents (within pragmatic and total sample size constraints) service users with experience of either face-to-face and/or virtual delivery, experience of different NERS pathways (generic or risk factor/disease specific), those who declined their NERS referral or virtual support when offered, and those living in different local authority areas. The NERS programme manager will collect initial expressions of interest from NERS service users and consent to share contact details with the research team. These will be provided to the team along with data which can be used to purposively select individuals from the criteria listed above. The research team will email potential participants consecutively with a link to our secure survey software REDCap (residing on the UH server). The email will be presented in both English and Welsh. This process will continue until sampling quotas for our criteria are filled. The research team will additionally use the NIHRs 'People in Research' portal to seek potential participants who were referred on to the NERS programme but declined to participate. The advert will be presented in both English and Welsh and will provide a link to the same REDCap study page. REDCap will be used to present participant information, collect informed consent and basic demographic information, and to book participants on to available interview time slots. Individuals will be able to choose to have all information/instructions on REDCap presented to them in either English or in Welsh (selection made on first entry to REDCap).
Inclusion/exclusion criteria: the following individuals will be eligible to participate

- NERS service users on the programme between 2019 – present, who have provided consent for WLGA to share their contact details with the PHIRST team
- Individuals referred on to the NERS programme between 2019- present who declined their referral

Setting
All data will be collected remotely using each participant's preferred mode (i.e. telephone, or

video conferencing software: Zoom or Microsoft Teams).

Procedure
Participants will be invited to take part in a semi-structured, in-depth interview undertaken by a member of the research team. All interviews will take place remotely. Participants will be able to choose to engage in the interviews online, using video conferencing software (Zoom or Microsoft Teams; audio only, or video plus audio), or by phone (mobile or landline). A Welsh-English interpreter will also be made available if required. Participants will be able use their own personal device or to access suitable equipment at the facility where they attend exercise sessions (Covid-19 restrictions permitting). In the latter case, these organisations will provide participants with a private space to conduct the interview, support in setting up Zoom, and assistance with IT issues (where available). A safeguarding protocol is in place and will be enacted as/when required (see below, ethics). The interviews are expected to last between 45 and 75 minutes. Audio recordings will be fully transcribed prior to analysis.

Analysis
The interview transcripts will be analysed using Framework Analysis (Gale et al., 2013) with an initial inductive coding approach. The themes and subthemes will then be mapped deductively in accordance with the socio-ecological approach (Sallis, 2015). The SEM is a theoretical model which focuses on the social and physical contexts of behaviour during critical evaluation of interventions.

4.5 Workstream 3: Quantitative outcome and health economic analysis

4.5.1 Uptake, engagement and retention

Research questions

2	Does offering a version of NERS in which some elements may be delivered virtually affect service-user uptake?
3	Does implementing different versions of NERS, in which either some or all elements are delivered virtually affect service-user engagement?
4	Does implementing different versions of NERS, in which either some or all elements are delivered virtually, affect service user retention?

Design
A longitudinal (baseline and 16week) observational design will be employed.

Primary outcomes:
The primary outcomes for workstream 3 are programme uptake, engagement and retention measured as follows.

Uptake will be measured as attendance at the consultation/first assessment and also at the first exercise session. Note, uptake data will not be presented for those on the virtual programme. This is because the virtual programme was only made available to service users who had already received a minimum of four weeks of the standard programme and had

therefore already passed these uptake benchmarks.

Engagement will be measured as the mean number of exercise sessions attended per week and will be available for all three groups. It is anticipated that, in addition to their being a significant proportion of missing data across all these measures, that engagement data in particular may be incomplete/unreliable. This is because this measure is not routinely or consistently recorded in the NERS database. Whether it is possible to answer research question two will therefore be assessed once the data is made available.

Retention will be measured as attendance at the 16-week assessment and will also be available for all three programmes.

Piloting
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Recruitment
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Sampling
Inclusion/exclusion criteria: data will be extracted from the NERS database for individuals within the three cohorts as defined in table 1 below.

Table 2. Characteristics of each of the three NERS cohorts

Cohort number	**Group**
Cohort one	Individuals referred on to the standard face-to-face version of the NERS programme who either, declined their referral, or accepted it and went on to receive the version offered (in full or part). Time period: during 2019-20; pre-pandemic.
Cohort two	Service users who initially accepted a referral on to the standard face-to-face programme but who were offered virtual delivery in response to the pandemic and then went on to receive that (in full or in part). Time period: during 2020-2021, in-pandemic.
Cohort three	Individuals referred on to the modified version of the NERS programme who either, declined their referral, or accepted it and went on to receive the version offered (in full or in part). Time period: during 2021-2022; in-pandemic.

Setting
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Procedure
Routinely collected monitoring and evaluation data will be used to answer the above research

questions. A data sharing agreement (DSA) with the joint data controllers (Public Health Wales, and the Welsh Local Government Association) will be executed prior to the secure transfer of pseudo-anonymised data to the research team. All data will be stored on the University of Hertfordshire's secure R drive and only accessible to those within the PHIRST team who are performing either data management or analysis roles.

Analysis

Hypotheses for RQ2 (What is the effect on user uptake of offering either the standard or modified programme?)	
H1	There is no difference in uptake between cohorts one and two (combined) and cohort three at 1) first consultation, and 2) first exercise session
H2	Uptake at 1) first consultation, and 2) first exercise session by cohorts one and two (combined) does not differ by demographic group (IMD, age, gender, local health board) or programme pathway
H3	Uptake at 1) first consultation, and 2) first exercise session by cohort three does not differ by demographic group (IMD, age, gender, local health board) or programme pathway

Hypotheses for RQ3 (What is the effect on user engagement of delivering either the standard virtual or modified programme?)	
H4	There is no difference in the mean number of exercise sessions attended per week between cohorts one, two or three
H5	The mean number of exercise sessions attended per week by service users in cohort one does not differ by demographic group (IMD, age, gender, local health board) or programme pathway
H6	The mean number of exercise sessions attended per week by service users in cohort two does not differ by demographic group (IMD, age, gender, local health board) or programme pathway
H7	The mean number of exercise sessions attended per week by service users in cohort three does not differ by demographic group (IMD, age, gender, local health board) or programme pathway

Hypotheses for RQ4 (What is the effect on user retention of delivering either the standard virtual or modified programme?	
H8	There is no difference in retention between cohorts one, two or three
H9	Retention for service users within cohort one does not differ by demographic group (IMD, age, gender, local health board) or programme pathway

H10	Retention for service users within cohort two does not differ by demographic group (IMD, age, gender, local health board) or programme pathway
H11	Retention for service users within cohort three does not differ by demographic group (IMD, age, gender, local health board) or programme pathway

Summary statistics will be calculated using standard measures such as means, medians and proportions as appropriate. Then relationships between outcome and explanatory variables will be investigated first with univariate tests and then by taking a multivariable approach. Where the three cohorts are compared, cohort will be included as a categorical explanatory variable.

Uptake and retention will be treated as binary (yes/ no) outcome variables. The chi-squared test or Fisher's exact test will be used for binary and categorical explanatory variables, and the Mann-Whitney U test for ordered explanatory variables. Continuous explanatory variables will be analysed using unpaired t-tests or the Mann-Whitney U test depending on whether or not observations approximate a Normal distribution. Following this, multivariable analyses will be performed using binary logistic regression. As a descriptive rather than predictive approach will be taken, explanatory variables will be entered into the model together.

Given the range of possible values, the number of exercise sessions attended will be treated as a continuous variable. The Mann-Whitney U test will be applied to binary explanatory variables, and Kruskal-Wallis one-way analysis of variance (ANOVA) will be applied to categorical explanatory variables. Relationships with continuous explanatory variables will be explored using simple linear regression. Following this, multivariable analyses will be performed in an exploratory manner using multiple linear regression.

4.5.2 Outcomes evaluation

Research question

5	Does implementing different versions of NERS, in which either some or all elements are delivered virtually, affect health and wellbeing outcomes?

Design
A longitudinal (baseline and 16week) observational design will be employed.

Primary outcomes:
The following primary outcome measures will be analysed (where available*):

- SPAQ (Scottish Physical Activity questionnaire)
- EQ-5D-5L (wellbeing)
- Sit to stand test
- Audit C (Alcohol)

- Height
- Weight
- BMI
- Blood Pressure
- Resting Heart Rate

It is anticipated that the physical activity and wellbeing data will be available for the majority of service users who reach their 16-week assessment on the standard, virtual and modified programmes. Whilst NERS routinely includes a further 52-week assessment, at the point of analysis, data from this assessment will not be available for either cohorts two or three. Comparisons based on 52-week data will therefore not included in the analysis.

*NERS provides ten different programme pathways to service users. All ten pathways include SPAQ and EQ5D outcome measures. The above list pertains to the generic pathway. Other pathways take different measures. Comparison across all pathways on all measures listed above may therefore not be possible. This will be assessed on receipt of data.

Piloting
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Recruitment
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Sampling
As described in 4.5.1

Setting
Not applicable. Routinely collected monitoring and evaluation data will be used for this analysis.

Procedure
As described in 4.5.1

Analysis

Hypotheses for RQ5 (What is the effect on health and wellbeing outcomes of delivering either the standard, virtual or modified programme?)	
H12	There is no difference in outcomes (mean change) between cohorts one, two or three
H13	Outcomes for service users within cohort one do not differ by demographic group (IMD, age, gender, local health board) or programme pathway
H14	Outcomes for service users within cohort two do not differ by demographic group (IMD, age, gender, local health board) or programme pathway

H15	Outcomes for service users within cohort three do not differ by demographic group (IMD, age, gender, local health board) or programme pathway

Descriptive statistics, such as means, medians and proportions will be provided. Change in outcome variables between baseline and 16 weeks will be investigated using univariate methods as described above, with techniques appropriate for the explanatory variable type (e.g., binary, continuous). In the multivariable analyses that follow, logistic regression with be used with binary outcomes, multinomial logistic regression will be applied to categorical/ ordinal outcomes with multivariable linear regression for continuous outcome variables. Where the three cohorts are compared, cohort will be included as a categorical explanatory variable.

The number of explanatory variables that can be incorporated into each multivariable analysis may be constrained by the number of participants in the dataset and completeness of data. If the data allow, the group factors explored will include demographic characteristics and pathway (e.g. generic, stroke, mental health). If the level of data completeness is sufficiently high, sensitivity analyses will be performed.

4.5.3 Economic/cost evaluation

Research question

6	What are the expected resources and corresponding costs (including impact on service user out-of-pocket expenses) of delivering core parts of the NERS programme, and do they differ for face-to-face and virtual delivery?

Design
Costing study

Method

Given the widely varying programme, we will consult with appropriate stakeholders to identify core programme elements (anticipated to be consultation/first assessment, 16-week assessment, 52-week assessment, and exercise sessions). The primary costing perspective will be that of NERS, that is, considering costs to NERS of employing staff and facility hire. For each identified element, we will liaise with appropriate NERS staff members to determine sub-activities involved (and any differences between face-to-face and virtual delivery); the typical duration of these sub-activities; the typical staff member delivering the sub-activity. In parallel, we will work with service leads to estimate an hourly cost of employment (including overheads such as NI contributions etc) for the different categories of NERS staff. Sub-activity durations will be multiplied by the appropriate hourly rate to estimate the cost of staff time to deliver the element. The staff time costs will be added to any facility hire costs incurred to calculate a total cost per element and any variation under the different programme types. We

will also note any staff feedback on the costing (such as unintended consequences or hidden costs).

We will also explore out-of-pocket expenses (identified elsewhere through qualitative interviews) incurred by service users and whether these differ between face-to-face and virtual delivery. This will likely be speculative, given such data is not routinely collected.

We will use the latest costing year for which costing resources are available, inflating from previous years as required.

We will expand the costing as useful and as health economic capacity permits – for example, perhaps costing an expected delivery of the generic pathway.

Analysis

For each element costed, we will tabulate the resources used in the sub-activities, their associated costs and calculate a total cost. Where these differ by programme type, we will compare and contrast the similarities and differences. We will summarise any feedback from NERS staff. Finally, we will highlight any suggested economic impacts arising from these costings.

Analysis of out-of-pocket expenses will depend on the volume and format of data collected in the qualitative interviews. Initially, we expect to tabulate the different reported costs under the associated delivery option (face-to-face and virtual delivery). We will compare and contrast the similarities and differences, and economic impacts they may have for future programme adaptions.

4.6 Workstream 4: Data synthesis and dissemination

Approaches to integrating qualitative and quantitative research procedures and data can be implemented at 'design', methods', and 'interpretation and reporting' stages of research (Fetters, Curry, & Creswell, 2013). For this study, qualitative and quantitative data will primarily be integrated at the 'interpretation and reporting' level. Qualitative and quantitative data will be separately analysed as standalone workstreams before being brought together (Brannen, 2005).

Coding and analysis of WS1 and WS2 data will begin prior to WS3 quantitative analysis commencing but some is likely to be conducted in parallel enabling a degree of 'cross-fertilisation'. Data will be integrated used an 'integrating through narrative' approach (Fetters, Curry, & Creswell, 2013), where qualitative and quantitative findings are described in different sections of the same report. A mixed contiguous/weaving approach will be taken (Fetters & Freshwater, 2015), allowing the research team to integrate findings from the quantitative outcomes and health economic analyses with qualitative analysis of staff and service users' experiences of remote and face-to-face service delivery. This will allow, for example, for the generation of explanations for patterns of engagement and outcomes, differences in costs, and for scrutiny of inequalities in access to services.

Recommendations will be generated by the research team, through consultation with the

Advisory Board, project-specific Advisory Group, the PIRg, and NERS Public Voice. Recommendations will be further developed with key NERS and WLGA stakeholders, including those who have accessed the programme, at a stakeholder workshop. The workshop will be facilitated by the Central PHIRST team and will make extensive use of group work and interactive, participatory methods to engage workshop participants in a collaborative decision-making process. This will help to ensure that the recommendations for future optimisation of NERS services generated by the evaluation are appropriate and feasible, fit within wider transformation plans, and that a range of stakeholders are involved in their co-production.

In terms of dissemination, Central PHIRST impact, implementation and dissemination work will be driven through the development of an 'Impact Map', 'Dissemination Strategy' and 'Implementation Plan'. The Impact Map will outline the different levels of implementation that will be conducted with different audiences and map the short, medium and longer-term impacts. The Impact Map will be developed in partnership with PHW, WLGA, the NERS team, PIRg members, NERS Public Voice and the project Advisory Board and Group. It will consider the value of findings to the wider public health system and its stakeholders and how outputs can be effectively communicated and mobilised to other regions and sectors. The Impact Map will capture how the outcomes will be used by the local authority to inform planning and delivery in the short, medium and long-term, and once developed, will define the criteria for strategic impact work and how this will be delivered.

Following development of the Impact Map, we will work with guidance from implementation experts in the East of England NIHR ARC, and the UH Marketing and Communications (MarComms) team, to develop a 'Dissemination Strategy' and 'Implementation Plan'. In addition, a dynamic database of stakeholders is being created and we will convene a 'design group' to test ideas for effective implementation and dissemination. Dissemination will occur through several key routes, including:

- A technical report and accompanying set of PowerPoint slides for Public Health Wales and the Welsh Local Government Association
- PHIRST website, jointly managed by the four PHIRST teams
- Creative outputs such as video and interactive content, including a video lay summary
- Social media channels
- Traditional academic routes of conference presentations and peer-reviewed, open access journal articles
- Dissemination through professional networks, including physical activity, sports, leisure and lifestyle improvement sector specific networks of which our project-specific Advisory Group are members

All outputs will be informed by consultation with the PIRg, NERS Public Voice, and the project Advisory group. In addition, to organize the collaboration within the four PHIRST teams across England, a national-level PHIRST Communications Working group has been set up with representatives from each PHIRST as well as PPI members (supported by the PPI co-applicant and PPI expertise from University of Hertfordshire). This team will meet regularly and develop proposals for the approval of NIHR.

5 Capacity building

An ambition of the Central PHIRST team is that all projects leave a positivity legacy for stakeholders which extends beyond the research outputs. As noted in work stream 1, we have appointed two service providers (NERS coordinators) to co-facilitate the focus groups and to contribute to qualitative data analysis. Full training and support will be provided. This will include the piloting of research materials, research ethics, focus group facilitation, framework analysis, and data interpretation. The purpose of this is to up-skill individuals from within the programme team who will then be able to repeat this aspect of evaluation in the future.

6 Research governance and project management

6.1 Central PHIRST governance and project management

Appendix B presents an organogram of the Central PHIRST showing the team structure and roles.

Project Leads

The project is led by two PHIRST co-investigators, Dr Katie Newby and Dr Neil Howlet, under the direction and supervision of the PHIRST Chief Investigators, Professor Katherine Brown and Professor Wendy Wills.

Management Group

The Central PHIRST Management Group meets on a weekly basis to provide oversight and guidance to the Central PHIRST. The Management Group comprises the Chief Investigators and the eight PHIRST Co-applicants listed in section 1.5.

Central PHIRST Public Involvement in Research group (PIRg)

The University of Hertfordshire is committed to involving the public in all stages of its research and has an existing Public Involvement in Research group (PIRg) comprised of members of the public, service users and carers. In collaboration with our PPI co-investigator Amander Wellings, we have set up a dedicated PHIRST PIRg, which is chaired by Amander and supported by Professor Julia Jones and members of the research team.

The PIRg will work closely with the Central PHIRST team and provide a public, service user and carer perspective to all the public health evaluation projects conducted by the team. The eight members of the PIRg meet on a monthly basis to discuss various aspects of Central PHIRST evaluation work (for example, research questions, methodology, literature review, research tools, and dissemination), and between meetings will work closely with the PHIRST to co-produce the evaluation.

6.2 PHIRST advisory groups

Central PHIRST Independent Advisory Board

An Independent Advisory Board (Central PHIRST Independent Advisory Board) has been convened to provide independent, external and policy-orientated advice to the Central PHIRST. The Board provides specific advice and support in relation to the strategic direction of the Central PHIRST and its allocated projects. It comments on the ongoing work plan and

progress in line with study protocols, acts as a sounding board for new ideas and developments and advises on opportunities for wider dissemination and for translating research into policy and practice. It is an advisory only body and does not make decisions in its own right or report to any other group or committee.

The Board will meet up to three times per year and is comprised of experts in the fields of public health and evaluation from academic, third sector, governmental and public sector backgrounds. It is comprised of the following members:

Name	Job title	Organisation
Mrs Helen King (Chair)	Former Deputy Director of Public Health / currently Independent Public Health Consultant	Solihull Public Health Department
Dr Nicola Armstrong	Programme Manager, HSC & R&D Division	Northern Ireland Public Health Agency
Professor Katherine Brown	Professor of Behaviour Change in Health	University of Hertfordshire (non-independent)
Mr Geoff Brown	CEO	Healthwatch Hertfordshire
Dr Tim Chadborn	Head of Behavioural Insights and Evaluation Lead	Public Health England
Dr Suzanne Connolly	Senior Health Improvement Manager	Public Health Scotland
Professor Steve Cummins	Co-Director of the Population Health Innovation Lab	The London School of Hygiene and Tropical Medicine
Dr Sarah Hotham	Senior Research Fellow & NIHR RDS SE Research Adviser	University of Kent
Professor Margaret Maxwell	Director of MHANP Research Unit	University of Stirling
Mrs Marion Cowe	PPI Expert by Experience on Central PHIRST Public Involvement In Research Group (PIRg)	Independent Member
Professor John Middleton	Professor of Public Health	Wolverhampton University
Professor Toby Prevost	Director, Nightingale-Saunders Clinical Trials & Epidemiology Unit at King's CTU	Kings College London
Mrs Genevieve Riley	Programme Manager	West of England Academic Health Science Network
Professor Richard Smith	Professor of Health Economics	University of Exeter
Professor Sarah Stewart-Brown	Professor of Public Health	University of Warwick

Dr Ruth Tennant	Director of Public Health	Solihull Metropolitan Borough Council
Mrs Amander Wellings	PPI Expert by Experience; Chair of Central PHIRST PIRg	University of Hertfordshire (non-independent)
Professor Wendy Wills	Director of the Centre for Research in Public Health and Community Care	University of Hertfordshire (non-independent)

Central PHIRST Wales NERS Evaluation Advisory Group

A project-specific Advisory Group has been convened to offer specific advice and support in relation to the Wales NERS evaluation. The Advisory Group will meet up to six times per year for the duration of the Wales NERS evaluation.

Name	Job title	Organisation
Andrew Thomas	Group Manager	Prevention and wellbeing, Social Services and Wellbeing Directorate
Sharon Davies	Head of Education	Welsh Local government Association
Dr Brian Johnson	Retired GP	
Bob Laventure	Director	Later Life Training
Pip Ford	Retired Previous job - Public Affairs and Policy Manager for the Chartered Society of Physiotherapy in Wales	
Claire Hurlin	Strategic Head of Community and Chronic Conditions Management	Hywel Dda Local Health Board
Dr Andy Prestwich	Senior Lecturer	University of Leeds
Dr Stef Williams	Chartered Psychologist	No assigned organisation
Prof Andy Jones	Professor in Public Health	UEA
Fiona Cunnah	Public Health Specialist working on the activity agenda within WG.	Welsh Government
[Name withheld]	PPI representative	
John Broughton (Chair)	PPI representative	
Carrol Lamouline	PPI representative	

Jeannie Wyatt Williams	National Exercise Referral Scheme Manager for wales	Welsh Local government Association
Elaine Scale	Policy Support Officer – National Exercise Referral Scheme	Welsh Local government Association
Mary-Anne McKibben	PHW Consultant in Public Health, Health Improvement Division,	Public Health Wales
Nicola Gordon	Principal Public Health Practitioner	Public Health Wales
Adam Fletcher	Head of British Heart Foundation Cymru	British Heart Foundation Cymru
Joanne Oliver	Health Systems Insight Manager - Wales	British Heart Foundation Cymru

7 Ethical considerations and approvals

Whilst an ethical framework guides the work of the PHIRST, ethical considerations for this project particularly relate to the qualitative process evaluation (workstreams 1 and 2) and the following sections therefore largely relate to these elements of the study.

This project approaches ethics as an ongoing reflexive exercise relevant to all aspects of data collection, analysis and publication. While the below provides a description of the ethical issues identified, it is possible that unexpected ethical issues will occur during the course of the research. The research team will monitor and document ethical concerns arising during the research which will be captured in the study's issue log. When necessary these will be discussed with partner organisations (in accordance with provisions of confidentiality). PPI input will be sought in any discussion about ethical matters at all stages of research, both routinely, as and when different forms and data collection instruments are developed, as well as when particular issues arise.

Informed Consent and withdrawal

All participants will be aged 16 years or older (inclusion criteria for NERS is aged 16 years or older). All potential participants in workstreams 1 and 2 will be provided with detailed Participant Information, which will convey comprehensive information about the project to allow them to provide informed consent. They will be requested to record this consent in an electronic format within REDCap. Participants will be informed about their right to withdraw from the study at any time.

Participant information will be written in a style of language that is accessible to participants. To ensure this, we will seek input/review from our PIRg. Furthermore, for service users, all written materials will be made available in Welsh, and a Welsh-English interpreter will be made available on request for interviews. A dedicated telephone number and email address will be set up for participants to contact the research team with queries.

Data protection

All data will be stored and processed in line with GDPR and our Data Protection Impact Assessment (DPIA). Data will be stored on our project-specific R drive (on UH server) and only accessible to those within the research team who require this. The R drive will be used to store details of those interested in participating in focus groups/interviews, audio recordings and transcripts of focus groups/interviews, and the programme monitoring and evaluation data provided by PHW/WLGA (required for work stream 3). Also see section 8 below (data protection and management)

Confidentiality

This project will maintain full participant confidentiality (although see limits to confidentiality in next section 'Risks, safeguarding and referrals'). Participants' contributions to the research will not be shared with service providers or their organisations and will be anonymized in publications. Focus group participants will be encouraged to consider their discussions confidential. Data provided by PHW/WLGA for work stream 3 will be pseudo-anonymised.

Risks, safeguarding and referrals

It is not expected that the nature of the project will give rise to safeguarding concerns beyond those of any other project. A PHIRST safeguarding protocol has been developed which will be used to guide decision-making /actions as and when necessary. A copy of the safeguarding protocol is available on request from the Chief Investigators. As there are under 18s within our sampling frame, we have procedures in place that enable us to safeguard these individuals if they disclose information that leads us to believe that they are at serious risk of harm. This could include ending our confidentiality agreement with them (this is clearly described in our participant information). Our safeguarding protocol includes detailed information on when and how to perform this.

Potential benefits for study participants

This project focuses on evaluating different delivery modes for NERS and will provide recommendations for how it should be delivered in the future. It is possible that organisations modify their service delivery based on the findings of this project. Thus, this is a rare opportunity for participants to see the effects of their participation in action. Participants will be informed that a report and video summary will be produced and disseminated that will contain recommendations. Service user participants will receive a voucher to thank them for their participation in the study.

Approvals

Ethics approval has been granted by the University of Hertfordshire Health, Science, Engineering & Technology ECDA.

Workstream 1			
	Required?	Protocol number	Date obtained
Institutional approval	Yes	LMS/SF/UH/04546	21/04/2021
Workstream 2			
	Required?	Protocol number	Date obtained
Institutional approval	Yes	LMS/SF/UH/04546	21/04/2021
Workstream 3			

	Required?	Protocol number	Date obtained
Institutional approval	Yes	LMS/SF/UH/04546	21/04/2021
Workstream 4			
	Required?	Protocol number	Date obtained
Institutional approval	No		

8 Data protection and management

The PHIRST is an NIHR funded initiative and the University of Hertfordshire is leading a consortium involving Ulster University, the University of Birmingham and the University of East Anglia. Staff at the University of Hertfordshire will take full responsibility for organising data collection and the safe management and storage of data.

A Data Protection Impact Assessment (DPIA) for this study has been produced and approved by the University of Hertfordshire's Data Compliance Officer. This document will be reviewed and updated regularly to meet University governance regulations. A copy of the DPIA is available on request from the Chief Investigators.

A Data Management Plan has been produced specifying the types of data that will be generated by the study, how this data will be preserved, and how it will be shared. The DMP will reflect the University of Hertfordshire's commitment to open access science. A copy of the DMP is available on request from the Chief Investigators.

9 Plain English Summary

Overview of the project being evaluated

The National Exercise Referral Scheme (NERS) is a Welsh Government programme that operates across the whole of Wales. It aims to help members of the public to improve their physical and mental health and wellbeing by providing access to personalised and supervised physical activity.

NERS is aimed at people aged 16 years and over, who are not used to taking part in physical activity or who are at risk of, or currently experiencing, a long-term health condition. People are referred onto NERS by a health professional such as a doctor, nurse or physiotherapist, and then take part in a 16-week programme of exercise sessions while being supported by a trained 'exercise professional'. The sessions are designed to be fun and easy to fit into everyday life.

Why this study is needed and what we are aiming to do

The Covid-19 pandemic meant that in March 2020 the NERS programme had to change the way it delivered its services. One of the main changes was that the it moved from running exercise sessions face-to-face to running them virtually (for example, with people joining in

with live sessions from their own homes while watching their instructor on a smartphone, tablet or computer).

The aim of the study is to understand whether this change in the way that NERS has been run has affected:

- whether people have joined NERS in the first place
- whether people have taken part in the sessions
- whether people have stayed involved for the full 16 weeks of the programme
- people's physical and mental health and wellbeing

We're also interested in finding out what service users and those delivering NERS think has worked well and not so well about running the programme in this new way. We aim to work with the NERS team to help them understand how the project might be best delivered in the future.

Research questions
The study aims to answer the following, broad research questions:

- How has delivering NERS virtually affected whether people join the project, take part in exercise sessions, and complete all 16 weeks of the programme

- Are there things that increase or decrease the chances of people joining and taking part in NERS, and what are these for different groups of people?

- How do the outcomes for service users who experience virtual NERS delivery compare with those for service users who experience it face-to-face? Do some groups of people have better outcomes than others when NERS is delivered virtually or face-to-face?

- How do the costs of running NERS virtually compare to the costs of running it face-to-face?

- What might be the best way to deliver NERS in the future and what might be the benefits and downsides of these different options?

Evaluation timescales
Start of evaluation work: January 2021
Draft final report completed: June 2022
Key dissemination activities completed: June 2022

The value of the findings

Public Health Wales and the Welsh Local Government Association (who jointly manage NERS), the Welsh Government, local authorities and other stakeholders involved in delivering NERS, and service users, will all benefit from this research. The knowledge produced will provide an understanding of how NERS might best be run in the future so that, as many people as possible can benefit, and positive outcomes are experienced equally by all. There are also

likely to be findings of value to similar exercise referral schemes, as well as for health improvement and promotion initiatives that aim to engage and retain service users in these types of programmes.

Research design

1) Asking staff who help deliver NERS to take part in group discussions
2) One-to-one interviews with NERS service users and people referred on to NERS but never took it up
3) Looking at information on health and wellbeing outcomes to see what has changed for those who took part in NERS and if this varies for different groups of service users (for example, those who experienced NERS virtually compared to those who experienced it face-to-face, and those with different health conditions)
4) Looking at how much virtual delivery costs compared to face-to-face delivery
5) Running a workshop to work together with those involved in NERS to explore the best way for NERS to be run in the future

Service users will be involved throughout the design of this project, adding their insight to help the researchers answer questions that are important to them. They will also help with understanding the results of this evaluation and with sharing them.

10 Project timescales/GANTT chart

Activity	Mar 21	Apr 21	May 21	June 21	July 21	Aug 21	Sept 21	Oct 21	Nov 21	Dec 21	Jan 22	Feb 22	Mar 22	April 22	May 22	June 22
DSA																
Protocol																
Ethics application			Decision in May													
Qual recruitment																
Qual data collection																
Qual data analysis																
Quant analysis (cohorts 1&2)																
Report writing																
Dissemination																

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12 Appendix

Appendix A – NERS decision making framework for modified programme

ALERT LEVEL			
	Not Vulnerable	Vulnerable	Extremely vulnerable
1. Alert level 1 (low risk)			
2. Alert level 2 (medium risk)			
3. Alert level 3 (high risk)			
4. Alert level 4 (very high risk)			

GREEN	Deliver face-to-face NERS provision, indoors and outdoors, unless there are site or group specific closures. The provider can offer virtual provision on a discretionary basis. Conduct initial and 16-week assessments face-to-face at the NERS venue, if possible (assuming well-ventilated premises and adequate PPE).
AMBER	Deliver face-to-face NERS provision outdoors only; otherwise, delivery is virtual. Conduct initial and 16-week assessments face-to-face at the NERS venue, if possible (assuming well-ventilated premises and adequate PPE).
RED	Deliver virtual provision only. Conduct all assessments virtually.

Framework taken from NERS Covid-19 Prevention and Response Plan published by Public Health Wales

Appendix B: Central PHIRST team organogram

NIHR | Public Health Intervention Responsive Studies Teams