NIHR | Public Health Intervention Responsive Studies Teams

PHIRST Fusion Evaluation of the North Yorkshire County Council Living Well Smokefree Service: a Hybrid Specialist Stop Smoking Service offering a blend of face-to-face and remote service provision

Study Title	PHIRST Fusion Evaluation of the North Yorkshire County Council Living Well Smokefree Service: a Hybrid Specialist Stop Smoking Service offering a blend of face-to-face and remote service provision
Study Period	December 2021 - April 2023 (16 months)
Study Design	Mixed Methods
Research Aim	The overall aim of the evaluation is to explore the feasibility and acceptability of the North Yorkshire County Council Living Well Smokefree Service (LWSF) hybrid smoking cessation service. It will look at whether hybrid and blended approaches are acceptable delivery models to service users and practitioners, are equitable and provide value for money.
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Abstract
This protocol outlines the approach and methods that will be used in the PHIRST Fusion evaluation of the North Yorkshire County Council Living Well Smokefree (LWSF) Service. The LWSF service offers a hybrid model, where smoking cessation support is provided either face-to-face, remotely, or through a blended (remote and face-to-face) pathway. The evaluation will employ a mixed methods approach using interviews and focus groups to collect primary qualitative data which will explore service staff and service user's perspectives and experiences of the hybrid LWSF service, and will use existing quantitative data to explore service monitoring and outcome measures. The findings of the evaluation will provide North Yorkshire County Council with evidence which will help them understand the acceptability and feasibility of the hybrid LWSF service, and which will help them shape current and future service delivery.

Contents

1.0 Background, contextual information, and overview of the intervention to be evaluated

1.1 Background to the PHIRST scheme

The study is funded by the National Institute for Health and Care Research (NIHR) and will be undertaken by the Public Health Intervention Responsive Studies Team (PHIRST) Fusion team. The PHIRST Fusion team's approach to evaluation follows a 5-step process: brokerage, work allocation, research, reporting & knowledge mobilisation, and continuous improvement, which includes evaluability assessment methodology and embedded research with local government practitioners.

This protocol outlines the approach and methods that will be used in the PHIRST Fusion evaluation of the North Yorkshire County Council Living Well Smokefree (LWSF) Service.

1.2 The Evaluability Assessment process

We have used evaluability assessment (EA) methods to co-develop the evaluation design. EA is a rapid, systematic, and collaborative way of deciding whether and how a programme can be evaluated, and at what potential cost. An EA was facilitated by PHIRST Fusion from December 2021 to May 2022. We undertook three workshops with key stakeholders involved with the LWSF service to ascertain their understanding of how the LWSF hybrid model will deliver a better service for people wishing to quit smoking. Each workshop lasted two hours. Workshop participants included: LWSF commissioners from the local council, managers of the LWSF service, local healthcare service partners from the NHS and voluntary community sector, LWSF smoking cessation advisers, and a public representative. During the workshops we explored:

- The underpinning aims and assumptions of the LWSF programme
- The LWSF programme theory of change (see appendix 1)
- Stakeholder thoughts and perspectives around how the LWSF service is/can be designed to provide smoking cessation support, and,
- What information is needed to inform future service development.

A feasibility evaluation study was agreed as the aim of the PHIRST Fusion evaluation.

The EA process supported the evaluation team to understand the service context.

1.3 Overview of the intervention to be evaluated and contextual information

Community stop smoking services are at the forefront of efforts to reduce premature death and disability due to smoking in the UK (ASH, 2022). 'Living Well Smokefree' (LWSF) is North Yorkshire County Council's programme to tackle smoking in the region. There are approximately 70,000 smokers within North Yorkshire, with higher rates being found in areas of greater deprivation, and worryingly, above national average rates of smoking in priority risk groups (such as during pregnancy and in populations with mental health conditions) (North Yorkshire tobacco control strategy, 2015). Working with people over the age of 12, the LWSF service offers one-to-one support over a 6-12 week period (one session per week) in an effort to achieve a Russell Standard quit (West, 2005). Support is provided to help service users set a quit date, and to manage cravings/withdrawal symptoms. Support includes pharmacotherapy (nicotine replacement therapy (NRT) medication vouchers provided by prescription), CO (carbon monoxide) monitoring, and every client has a named key worker (smoking cessation adviser) who employs Motivational Interviewing principles and

techniques to increase self-efficacy to reduce smoking.

Stop smoking services around the UK have had to adapt to the effects of the COVID-19 pandemic. The LWSF service found itself in the situation of needing to change how it delivered support; it moved from face-to-face provision (which was the main method of engaging service users) to predominantly remote delivery, with support being delivered in virtual formats (voice/video call). In the EA process, the service team reported that they have seen remote delivery as having benefits for both staff and service users (e.g., convenience, increased accessibility for rural communities), as well as challenges (e.g., difficulty in achieving/recording CO validated quits, digital inequalities reducing engagement for some populations). As COVID-19 restrictions eased, to retain the positives and ameliorate the negatives, the LWSF provider and commissioners would like to develop and implement a 'hybrid' approach. This hybrid approach would include three service delivery modalities:

- Face-to-face where smoking cessation support is offered in person face-to-face
- 'Remote' where smoking cessation support is offered via voice/video calls
- 'Blended' where smoking cessation support is offered via a combination of face-to-face and voice/video call approaches

In the EA process, a theory of change for the hybrid LWSF was co-developed with LWSF stakeholders (Appendix 1: Living Well Smokefree Theory of Change). It is assumed that a hybrid model will increase access to the LWSF service, better target and engage different 'priority groups' and thus increase engagement from service users and result in better outcomes (i.e., increased quitting rates over the short-term, and reduced smoking rates over the long-term). From the EA assessment, the LWSF service identified target and priority groups as: pregnant women; people with mental health conditions; substance misuse treatment users; secondary care groups; primary care groups; people with long-term health conditions (e.g., respiratory, vascular, cardiac). The hybrid service would ideally be designed to maximise effectiveness and equity in supporting people in these groups to quit smoking. Thus, a hybrid approach is seen as potentially providing a better use of limited service resources.

The main question identified from the EA assessment was how the new hybrid service might be most effectively and equitably implemented. Two avenues of interest were identified in the EA sessions: qualitative exploration of key stakeholders (staff and service users) perspectives of the LWSF programme, and the quantitative exploration of routinely collected LWSF service data. The focus of this project will be on evaluating the feasibility and acceptability of the North Yorkshire County Council LWSF hybrid smoking cessation service. It will explore which groups face-to-face, remote or blended approaches are the most appropriate for. Using routinely collected service outcome and monitoring data, as well as primary qualitative data, we have the ability to examine the impact offering different service modalities has upon service users, staff and service outcome measures such as staff and patient experience and quitting success. Based on the EA process, the evaluation will take a formative rather than summative approach, with two-way engagement between the evaluation and service teams. The findings of the research will help shape and inform how the LWSF service could be delivered to meet the service standards and objectives. Beyond the local service landscape, smoking cessation services more generally will benefit from the translational knowledge produced.

2.0 Review of existing evidence

Globally, smoking is a major public health issue (WHO, 2017a), and is a leading cause of preventable death, avoidable physical health issues/conditions (WHO, 2017b), as well as a considerable driver of health inequalities (ASH, 2021; NHS, 2019). Despite smoking prevalence falling nationally in the UK over the past few decades (NHS, 2019), smoking rates have plateaued for some people and places (Mardle et al., 2012; NHS, 2019; Di Cesare et al., 2013), with higher rates for those from the most deprived contexts and little reduction in socioeconomic inequalities in smoking (Hiscock et al., 2010). There are higher levels of smoking in specific populations, such as people with mental health issues (Spanakis et al., 2021), as well as worrying rates of people smoking during pregnancy (NHS Digital, 2021). In the UK, smoking cessation support is often provided through NHS services (e.g., GP practices), community pharmacies, and commissioned smoking cessation services. It is well established that engagement in smoking cessation services, support and activities have beneficial reductions in smoking rates, and associated improvements in health (Thomsen et al., 2014). However, higher smoking rates in specific populations and lower quit rates for the most disadvantaged groups (Amos et al., 2011) suggests service provision and approaches need to be better targeted and flexible to further access, support and meet the needs of such populations.

During the COVID-19 pandemic, many smoking cessations services were required to adapt and move to 'remote' delivery models (i.e., way from face-to-face provision towards online and phone-based provision) in order to continue providing support in a context of social distancing (ASH, 2021a,b; Mahoney et al., 2021; Vinci et al., 2022; Vera San Juan et al., 2021). Indeed, there has been a wide adoption and implementation of remote provision, e.g., phone, text, email, video-conferencing methods, apps (see Haluza et al., 2020; Wu et al., 2021; Siemer et al., 2020; Crane et al., 2018) to facilitate the remote delivery of support. Remote approaches have long been mooted as a promising approach for delivering smoking cessation support (Byaruhanga et al., 2020; Ekeland et al., 2010; Vera San Juan et al., 2021; Appleton et al., 2021; Matkin et al., 2019; Danielson et al., 2014; Bennett et al., 2016; Kim et al., 2018). Such approaches are noted to provide flexibility and accessibility to smoking cessation support (Getty et al., 2019; Ash, 2021a; Vera San Juan et al., 2021; Vinci et al., 2022), reduce treatment gaps, as well as being a cost-effective (time and financial) approach (Getty et al., 2019; Matkin et al., 2019) (e.g., reduced staff time to deliver support to hard-to-reach/rural communities, and convenient around reduced service user time required to attend/access support (Siemer et al., 2020; Byaruhanga et al., 2020; Vera San Juan et al., 2020; Mahoney et al., 2021), and ultimately potentially helping reduce future burden on health services (Alqahtani et al., 2021). Remote approaches have been suggested to help eliminate barriers to access and engagement (Tzelepis et al., 2019), including travel times and costs (Tall et al., 2015; Byaruhanga et al., 2020), especially for rural populations/communities and those who struggle to access services in person (Carlson et al., 2012; Byaruhanga et al., 2020, 2021; Vinci et al., 2022).

Despite such benefits, there have been concerns around remote provision in terms of its feasibility for different population groups, whether service staff can adequately provide support over such mediums, and whether there is resource available to deliver such provision (Vinci et al., 2022). Indeed, important trade-offs are noted to exist between remote and face-to-face approaches (Appleton et al., 2021), with remote approaches suggested to impact upon rapport building, reducing the development of therapeutic relationships, reducing privacy and reducing engagement

levels, as well as reducing accountability to engage in sessions and fidelity of physiological testing (Appleton et al., 2021; Vera San Juan et al., 2021; Mahoney et al., 2021). Interpersonal contact and relationships are important in engagement, supporting, motivating and encouraging health behaviour change (Michael et al., 1998; Celio et al., 2017; Cheuvront, 1998; Wilhelmsen et al., 2013). Within remote approaches, video calls have been seen to offer more 'personal' and 'interactive' experiences than voice calls (Mahoney et al., 2021; Byaruhanga et al., 2021), resulting in higher rates of service user engagement/retention (Kim et al., 2018). Whilst rapport has been noted as being possible to develop using remote means only (Cruvinel et al., 2019), providers' skills and confidence in delivering remote support are important (Vera San Juan et al., 2020). Further barriers to remote delivery in the literature include digital exclusion, and concerns around if different populations can access treatment via remote means.

Remote provision has been noted as having comparable efficacy to face-to-face approaches in terms of treatment outcomes and treatment adherence (Siemer et al., 2020; Nomura et al., 2019; Carlson et al., 2012; Zwar et al., 2015). There is evidence that providers of remote provision have generally positive perspectives around acceptability and feasibility (Connolly et al., 2020; Bennett et al., 2016; Appleton et al., 2021; Kim et al., 2018), as well as generally positive perceptions and experiences from service users (Vera San Juan et al., 2021; Kim et al., 2016; Richter et al., 2015). The successful use of remote provision has been reported over a range of service user populations (Hilty et al., 2013; Ormston et al., 2015; Bennett et al., 2014; Joyce et al., 2021; Ashton et al., 2015), and noted as a preferable approach for some (Appleton et al., 2021). Indeed, for some specific populations, e.g., pregnant women (Joyce et al., 2021; Bennet et al., 2016), remote provision can be acceptable, feasible and useful.

There is a dearth of studies looking specifically at the comparison of in-person, remote and 'blended' smoking cessation treatment provision (for exceptions see, Siemer et al., 2020; Nomura et al., 2019). More work is needed to explore if, and to what extent, remote provision is effective - in terms of resulting in higher successful smoking quit rates long-term - cost-effective, feasible and acceptable compared to face-to-face approaches (Nomura et al., 2019; Mahoney et al., 2021; Mardle et al., 2012; Vera San Juan et al., 2021). Further, there is little known about service users' experiences' of 'blended' smoking cessation provision (Siemer et al., 2020b), e.g., support including both remote and face-to-face provision; there is greater research looking at blended mental health provision (Kooistra et al., 2016; Wilhelmsen et al., 2013; Vera San Juan et al., 2021; Appleton et al., 2021), which suggests generally positive perceptions. Thus, it is important to explore and understand the acceptability of different approaches for different groups, to look at in which contexts and for which populations remote provision may be employed; this will help design service provision, which is feasible, acceptable and effective for those delivering and receiving it. Further, it is also important to see if remote provision is an effective offering beyond the COVID-19 pandemic, or if it was simply valued as a consequence and thus accepted due to the conditions of the pandemic (Vera San Juan et al., 2021).

3.0 Evaluation Aim and Objectives

The aim and objectives were informed by the EA process with the North Yorkshire County Council LWSF smoking cessation service, and the literature review.

The overall aim of the evaluation is to explore the feasibility and acceptability of the North Yorkshire County Council LWSF hybrid smoking cessation service. It will look at if hybrid and blended approaches are acceptable delivery models to service users and practitioners, are equitable and provide value for money.

The evaluation will take a formative approach, with two-way engagement with the LWSF service team to support their reflection on changes to the initially implemented service model.

To inform the LWSF service team, the overarching questions will be:

- What are the strengths/weaknesses of the hybrid LWSF approach (face-to-face, remote, blended pathways)?
- How can the hybrid LWSF service be adapted and improved?

These overarching research questions will be informed by the following four research questions and associated objectives:

<u>3.1 Acceptability to staff</u>

RQ1 What is the acceptability of the hybrid LWSF service to delivery staff?

- What are the facilitators and barriers to delivering the LWSF service?
- What are the experiences and perspectives of service providers regarding face-to-face/remote/blended smoking cessation provision approaches?
- What are the perceived implications of the LWSF hybrid model on programme uptake, engagement, and delivery?
- What are the perceptions of how the service meets the needs of different clients/ different priority groups?
- What are the rationale/underpinning assumptions behind the application of different modalities for different groups?
- How is service provided/offered to service users

Objectives

- To conduct focus groups with service staff and key service stakeholders

<u>3.2 Equity and acceptability to service users</u>

RQ2 What is the acceptability of the hybrid LWSF service to service users?

- What are the facilitators and barriers to participating in the LWSF service?

- What are the experiences and perspectives of participants regarding face-to-face/blended/remote smoking cessation provision approaches?
- What factors would make the LWSF service more acceptable/engaging?

Objectives:

- To conduct interviews with service user groups (including non-target and target/priority groups)

3.3 Engagement and Effectiveness

RQ3 To what extent are the different pathways utilised by and effective for different client groups?

- What is the uptake of each pathway within the target groups?
- What is the drop-off/LTFU (Lost To Follow Up) for target/non-target groups?
- What are the rates of quitting achieved in the different pathways?

Objectives:

- To extend the existing routine monitoring data of service outputs and outcomes by splitting the data by the three pathway options (face-to-face, remote, blended).
- To produce descriptive statistics that describe the variation among client groups in the uptake of each pathway, loss to follow-up and 4-week quit rates.
- To explore the possibility of using client-level data to conduct a statistical analysis of variation in 4-week quit success between the three pathways, adjusting for key client characteristics.

3.4 Value for money

RQ4 How does the change to a hybrid LWSF service affect overall service value for money in terms of the cost per 4-week quit?

- What is the additional cost to the service of offering clients both remote and face-to-face options?
- How does the cost per 4-week quit of the service as a whole change over the course of implementing the new hybrid service?

Objectives

- To determine the additional cost of providing the face-to-face service option (in terms of room hire, staff travel, administration and management)
- To estimate a monthly cost per 4-week quit of the service and to show how this metric changed due to the new hybrid service.
- To interpret the change in cost per quit in light of the findings from Q1-Q3.

4.0 Methods

This study involves a mixed methods approach. We will collect primary qualitative data from focus groups with service staff and other key stakeholders (including service providers, managers, commissionaires, smoking cessation advisers, associated health care service staff), and interviews with service users currently involved in the LWSF service (from non-target and target/priority groups including those receiving remote, blended and/or face-to-face provision), looking at their perspectives and experiences of the LWSF hybrid service (RQ1 & RQ2). We will also use routinely collected LWSF service data to undertake descriptive data analysis of service outputs and outcomes, and explore the possibility of undertaking statistical analysis of quit outcomes among different pathways, and investigate differences among priority client groups (RQ3). Finally, we will investigate how the value for money of the new hybrid service offering by looking over time at how the overall service cost per quit changes over the course of implementing the new service (RQ4).

The quantitative and qualitative data are designed to inform our research questions (see above). Both types of data collection will therefore have an emphasis on understanding variation in service use, experiences and outcomes among different service modalities and service user groups.

- The feasibility and acceptability of the hybrid LWSF service will be examined through qualitative focus groups with service staff and other key stakeholders, and through interviewers with service users (RQ 1,2).
- The quantitative analysis of routine data will be used to explore RQ3,4.
- The qualitative and quantitative data will be brought together to help draw out learning points (overarching RQ).

4.1 Qualitative data collection

The overall aim of the qualitative data collection is to understand staff and service users' perspectives on the hybrid LWSF service's offering of different modes of provision. This will provide data to inform refinements to how the service is implemented.

4.1.1 Service staff focus groups

The acceptability and feasibility of LWSF to delivery staff (RQ1) will be examined through qualitative focus groups. Up to 10 service staff delivering the hybrid LWSF service (e.g., smoking cessation advisers, service admin workers), and up to 5 professional stakeholders involved in the development and running of the hybrid LWSF service (e.g., service providers, service commissioners), will be purposively recruited to participate in two separate focus groups (one for service staff and one for professional stakeholders) during the hybrid LWSF service set up. These focus groups will then be repeated as part of a mid-point review in December 2022 to understand how perspectives may have changed through the service implementation. Sampling aims to incorporate a variety of perspectives, and recruitment will be supported by our LWSF project partners who will facilitate recruitment and dissemination of study information and information sheets to potential participants. Participation will be voluntary; those who have expressed interest in taking part and who have read the information sheet and completed a consent form will be eligible to participate.

Focus groups will take place during one of the monthly LWSF service team meetings, in a private group room. Focus groups will take place either face-to-face, or online via a video call. Focus groups will be moderated by members of the research team. Focus groups will last around 120 minutes.

The recruitment materials and topic guides will be developed with our LWSF project partners. We anticipate the topic guide will explore:

- the facilitators and barriers to delivering the hybrid LWSF programme
- the experiences and perspectives of service providers regarding face-to-face/blended/remote smoking cessation provision approaches
- perceptions of how the service meets the needs of different clients/ different priority groups
- Expectations, outcomes, and encountered challenges of implementing and delivering the hybrid service
- what works well/what could be improved
- comparison to previous approaches
- thoughts on how to improve future service provision (e.g., how best to deliver hybrid models, and for which groups)

4.1.2 Service users interviews

The acceptability and feasibility of LWSF to service users (RQ2) will be examined through qualitative interviews. Up to 40 service users (including 20 non-priority group participants, and 20 priority/target group participants (priority groups include: pregnant women; people with mental health conditions; substance misuse treatment users; secondary care groups; primary care groups; people with long-term health conditions) will be recruited.

Potential participants will be recruited through our LWSF project partners. Smoking cessation advisors will help to recruit service users to participate in interviews; they will speak to LWSF service users during their sessions and ask them if they are interested in taking part in an interview with the research team regarding their thoughts and experiences of the hybrid LWSF service. Those interested will be given an information and consent form by our LWSF colleagues who will also collect service user consent to share their contact details with the research team. Potential participant contact information will be recorded on a password protected spreadsheet on the University of Sheffield secure drive. This information will also be accompanied with information which can be used to purposively select individuals (i.e., if they are in a priority/target group).

The research team will then contact the potential participants after seven days via phone/email to discuss participation. This will provide potential participants time to study the information sheet and contact relevant parties to ask questions about the research/participating. This process will continue until we have an adequate number of participants. LWSF advisors will be provided with information by the research team to verbally describe the research to service users. Participation will be voluntary; all service users receiving treatment from the LWSF service during the data collection period who have expressed interest in taking part and who have read the information sheet and completed a consent form will be eligible to participate.

Interviews will take place either face-to-face, over the phone, or online via a video call. The interviews will be organised around what is most suitable and preferred by the participant.

Participants will be able to use their own personal devices to participate in the interview. If face-to-face, our LWSF project partners will provide a private room to conduct the interview in the buildings/spaces where they usually host their sessions. A safeguarding protocol developed in collaboration with our LWSF project partners will be in place for both online and in-person data collection. Interviews will last around 30 minutes.

The recruitment materials and topic guides will be developed with our LWSF project partners and PPI group. We anticipate the topic guide will explore:

- experiences and perspectives of participants regarding face-to-face/blended/remote smoking cessation provision approaches
- the facilitators and barriers to participating in LWSF programme
- what works well/what could be improved
- thoughts on future service provision

Service users who take part in the interviews will be offered a £15 voucher as a thank you for their time.

4.1.3. Analysis

The focus groups and interviews, with the participants' consent, will be audio recorded, and transcribed verbatim. An inductive thematic analysis will be conducted, informed by Braun and Clarke's (2006) six stage thematic analysis approach. This involves: Step 1: Become familiar with the data, Step 2: Generate initial codes, Step 3: Search for themes, Step 4: Reviewing themes, Step 5: Defining themes, Step 6: Write-up. The research team will read a small selection of transcripts, and meet to review and discuss initial codes, from this we will produce a conceptual coding framework of key themes and sub-themes. The transcripts will be coded using NVivo software. The research team will meet regularly to discuss and amend the coding framework. The data will be explored to look at the feasibility and acceptability of the hybrid LWSF programme, and to draw out key learnings for service development and improvement.

4.2 Quantitative data collection

The overall aim of quantitative data collection and use in the evaluation is to understand the change to service effectiveness and value for money brought about by the introduction of the new hybrid service. Part of this aim is to understand how service effectiveness is influenced by the effect that the new hybrid service has on quitting rates in priority client groups. Descriptive statistics will be produced that show how service outputs and quitting outcomes differ among routes of referral and priority client groups (Q3). We will also explore how the new hybrid pathways affect the overall cost per quit of the service (Q4). To achieve this aim, we will use routinely collected data collected by the LWSF service on service user engagement, quitting outcomes at 4 weeks and the costs of service implementation.

4.2.1 Existing data already routinely collected by the LWSF service

Data on service outputs and quitting outcomes is routinely collected on the QuitManager electronic record system and meets the reporting requirements of NHS Digital. The LWSF team regularly analyse their service outputs and quitting outcomes using MS Excel to cross-tabulate by client

characteristics, source of referral, pharmacotherapy use etc. The LWSF service also has an online dashboard that presents this information graphically and tabularly based on an established service performance framework.

Through discussions with the service team, the following data items were identified as essential for the evaluation (Table 1).

Table 1. Data items to be derived from the data in QUITManager that would be essential for the evaluation.

Item	**Description**
Number of clients accessing the service as a whole	Key descriptors: - The number of individuals referred to the service (e.g. number of referrals / self-referrals). - The number of clients who subsequently access the service, defined by reaching the point where they can choose a mode of contact with the service.
Mode of contact with the service (choice between remote, face-to-face or hybrid service pathways)	A new field will be added to the QUITManager system. This will be used to stratify service outputs and outcomes by the three pathways that form the new hybrid service. From this the number of clients initially choosing each pathway can be calculated.
Number of quit dates set	Indicator that a client is making an attempt to quit smoking.
Number of renewed quit attempts	Indicator that the initial quit attempt failed and a new attempt was begun
Number of clients lost to follow-up	Client no longer contactable. If a quit date has been set, then the quitting outcome is unknown.
Quit outcomes (4 week quit is the primary outcome for evaluation)	Percentage of 4-week quits among clients who set a quit date. If CO validation of quits is routinely taking place across the service, then quit outcomes could be defined as CO validated 4 week quits.

Client characteristics (priority groups)	● Age (under 18, 18-34, 35-44, 45-59, 60+) ● Gender ● Ethnicity / Country of origin ● Occupational status (priority group is routine and manual) ● Pregnancy status ● Smoking history (number of cigarettes per day, date last smoked, number of quit attempts in previous year, Fagerstrom score, time from waking to first smoking) ● Mental health (Possibly from referral forms from health professionals. Key conditions might be learning disability / autism) ● Substance misuse (Possibly from referral forms from health professionals) ● Long-term health conditions (especially COPD and anything related to respiratory health / asthma. Heart attacks / strokes)
Source of referral	● Hospital ● Self-referral - *majority* ● Maternity services ● Primary care - specific GPs and pharmacies do deliver their own services - refer to LWSF if over capacity

4.2.2 Analysis

Effectiveness

The quantitative data will be descriptive in nature, and will involve simple quantitative analysis.

Descriptive summary statistics will be produced that show:

- Numbers and percentages of clients choosing each pathway option at their first consultation
- Numbers and percentages of clients who subsequently switch from phone only or in-person only to hybrid
- Numbers and percentages of clients who set a quit date and subsequently achieve a 4 week quit.
- How these numbers are split by priority client groups and source of referral

If the data is of sufficient size and quality and information governance approvals are in place, then we will explore the possibility of conducting a more detailed statistical analysis of how the likelihood of achieving a 4 week quit varies by pathway (remote, face-to-face, hybrid). This statistical analysis will allow investigation of how key client characteristics and source of referral interact with pathway type to determine quitting outcomes.

Value for money

The cost of providing a hybrid service will be estimated in terms of the additional cost of factors including room hire, staff travel, administration and management. Some of these costs will be variable, i.e., will go up or down depending on the number of clients choosing each pathway option (e.g. staff travel to clients). Some costs will be fixed, routinely incurred costs of maintaining the service (e.g. venue hire for face-to-face sessions). We will explore with the service the possibility of obtaining monthly estimates of these costs. We will also explore the possibility of estimating the sunk costs of setting up the new hybrid service (i.e. one-off investment costs), which could be included as a sensitivity in the estimation of service value for money as this could be of interest to commissioners.

To calculate a monthly cost per 4-week quit of the service, we will estimate the monthly service cost (with and without including the sunk costs) and divide this by the monthly number of 4-week quits recorded by the service. This method is designed to be based on the method already used to compute the cost per quit of the service. We will not attempt to compute the cost per quit separately for each of the three pathways of the new hybrid service. Instead, we will investigate how the overall service cost per quit varies over time as the new hybrid service is implemented and becomes established. This could be informative to the service by indicating the trajectory of change in service value for money.

4.3 Mid-point review

The qualitative and quantitative data will be separately analysed, before being brought together at a mid-point review, where interim findings will be presented to the LWSF service managers and commissioners to feed into service design (see timeline below). This mid-point review will generate recommendations based on the emerging data, which can be used to shape current and future LWSF service provision. Data collection of both qualitative and quantitative data will continue following the mid-point review.

There is potential to extend quantitative data collection beyond the project end date (March 2023), in order to support our knowledge mobilisation plan of upskilling council and LWSF team members to continue aspects of the evaluation for continued development (see below - Principle 3: design the research to incorporate the expertise of knowledge users). This will enable the LWSF service to collect and analyse more data about the hybrid programme beyond the project's duration. Options for continued analysis will be discussed with our project partners during the mid-point review when we have a clearer understanding of collected data.

4.4 Co-production and knowledge mobilisation

Building on the EA process, our work and joint decision-making with our project partners will continue to shape our protocol, research design and knowledge mobilisation. Our collaborative approach relates to NIHR School for Public Health Research knowledge-sharing principles (School for Public Health Research, 2018).

Principle 1: clarify purpose and knowledge-sharing goals

During the evaluation, we will aim to share knowledge by working co-productively to provide evidence and insight for a range of stakeholders. The evaluation will support work by those in North Yorkshire County Council coordinating and commissioning their LWSF programme. We are working to achieve our knowledge-sharing aim in a number of ways.

Principle 2: identify knowledge users

The most direct organisational knowledge users are the LWSF delivery team and commissioners of the programme in the local authority's Public Health team with responsibility for this area of activity. In addition, linked local authority teams, including data analysts, and Councillors with responsibility for policy areas that include the LWSF programme will be knowledge users with the Council. Wider knowledge users will include regional and national smoking advisors in the NHS, community-based NHS services (e.g. GPs), and organisations with a policy or campaigning interest in provision of LWSF activities including those in the voluntary and community sector. Members of the public who benefit from the LWSF programme will be both informants in the evaluation, and knowledge users of the evaluation's findings. The evaluation will also be of interest to the academic community.

Principle 3: design the research to incorporate the expertise of knowledge users

The EA process, and ongoing discussions with members of the LWSF team, have influenced the research design. Our approach has been agreed with local stakeholders responsible for the LWSF programme. A key contact in the LSWF programme will be part of the project team, this will enable them to co-produce all aspects of the work, and support with data collection, facilitation of the project, refining project tools (e.g., information sheets, topic guides), and recruitment. This approach will hopefully help to upskill council and LWSF team members, to enable them to conduct and repeat aspects of the evaluation once the project has come to a close, due to close involvement in the methodology. The formative evaluation design incorporates a formal mid-point check-in by the research team with key knowledge users, the format and scope of which will be agreed during the first part of the evaluation.

Principle 4: agree expectations

Given the diversity of proposed participants and the novel nature of the proposed hybrid and flexible service offer, we anticipate gathering a range of viewpoints. This range of views is important to capture and report, and local stakeholders are aware and supportive of our approach that aims to engage and account for a diversity of perspectives. We will continue discussions with local knowledge users about options for increasing the usefulness and accessibility of knowledge from the evaluation, and to support the implementation of findings in the design and delivery of services. The outcome of these discussions will be reflected in a knowledge mobilisation plan, initial elements of which are outlined in the outputs section below.

Principles 5 and 6: monitor, reflect, be responsive

We are developing a framework to evaluate knowledge mobilisation activities, in line with SPHR knowledge-sharing principle 5, 'monitor, reflect, be responsive' (School for Public Health Research

2018). This might involve a contribution analysis methodology. These initial ideas will be worked through with local stakeholders in the LSWF programme in North Yorkshire. The aim will be to assess how far knowledge mobilisation activities contribute to the uptake, use and impact of the evaluation research, and to provide a legacy (SPHR knowledge-sharing principle 6) in North Yorkshire, evidence of which will be generated in a post-evaluation review.

4.5 PPI (patient and public involvement)

We will ask our LWSF partners to set up a PPI group of service users (up to 5 service users) and relevant professional stakeholders (e.g., from linked-services such as Mental Health services), who can help advise on the project information sheets and topic guides. This advice could be especially important for understanding how to best approach clients from certain priority groups (e.g., with mental health conditions). Recruitment will be undertaken by our LWSF project partners. We envisage this to be a one-off session where they advise on the readability, accessibility and suitability of the project documents, but, depending on their availability and willingness to participate, we may work with the group to critically discuss emerging findings, advise on lay summaries and implication of findings, and on dissemination, ensuring it is appropriate. This group will be set up specifically for this project, but it is hoped that the LWSF service will continue this approach for reflecting on any future service adaptations.

5.0 Data management plan

The University of Sheffield will be the data controller for this study.

Qualitative data:
The project will generate qualitative data in the form of focus groups and interview transcripts. All focus groups/interviews will be audio recorded only, using an encrypted digital dictaphone. Audio files from interviews and focus groups will be uploaded to an access-restricted folder on the University of Sheffield server, as soon as is reasonably possible. Once uploaded, they will be deleted from recorders. Transcription of interviews/focus groups will be undertaken by an approved transcription company. The rest of the project team, including those who may become part of the team in the future, will also have access to the study's data and will be able to comment on data at the analysis stage. Access to data will be restricted to these individuals. To enable anonymity, transcripts will have a unique identifier embedded in the filename.

Quantitative data:
Data from QuitManager will be fully anonymised and securely transferred to the research team for analysis. Quantitative data will be collected/transferred using a data sharing agreement between North Yorkshire County Council's/LWSF and the University of Sheffield to enable the transfer of routine data. All data will be transferred over secure, encrypted connections. Data will be anonymised before being transferred.

All data analysis will take place on password protected computers/laptops of the research team if they are working away from the University. No data will be stored on computers/laptops but accessed via the University secure remote desktop.

Personal information will be collected as part of the qualitative research via consent forms and when arranging the interviews/focus groups.

- For consent forms: participants' names will be recorded on consent forms. Consent forms will be scanned onto and stored securely in a restricted folder on the University of Sheffield's secure drive. Any paper copies of consent forms will then be destroyed by shredding and confidential waste disposal. Consent forms will be securely stored for 10 years and then deleted.
- When arranging interviews/focus groups: The names of participants, contact details (if applicable) and times/dates of the data collection sessions will be recorded in a password protected spreadsheet on the University of Sheffield's secure drive. This information will be recorded for organising the data collection. This information will not be used in analysis or dissemination, and will only be used for project management purposes. Participant names and contact information will be deleted as soon as possible from this spreadsheet following participation of each participant.

General project documents will be stored either in a team google drive, or in a secure folder on the University of Sheffield secure Unidrive. Any personal information will be stored in password protected folders/documents on the secure drive. This includes contact information for participants, consent forms, audio recordings and transcripts.

Anonymised data will not be destroyed following completion of the study but kept available for future research in ORDA the University of Sheffield's Research Data Repository.

6.0 Ethics

Ethical approval will be sought from the University of Sheffield School of Health and Related Research.

The research team will ensure that issues of consent, confidentiality, safeguarding and data management are appropriately addressed across all aspects of the research process including recruitment, data collection, analysis and dissemination.

- Informed consent
    - All participants will be provided with a verbal description of the research, as well as an information sheet detailing the project. All participants will be provided time to read the information sheet and consider participation, as well as time and research contact details to ask any questions they may have about the study/participating.
    - All participants will be required to sign a consent form before participating.
    - All participants will be informed of their rights to withdraw from participation.
- Confidentiality
    - Participants' confidentiality will be maintained throughout the project (with the limits of confidentiality being explained to all participants e.g., the need to break confidentiality if a safeguarding issue arises, the inability to maintain confidentiality due to the nature of focus groups).
    - Participants will be anonymised in all outputs, and any interviews/focus groups participants will not be linked to any direct quotes.
- Safeguarding protocol
    - Due to the nature of the project (exploring perceptions of the hybrid LWSF service), we do not anticipate any safeguarding issues to arise from discussions. However, a safeguarding protocol has been developed in collaboration with our LWSF project partners. This includes having a named North Yorkshire County Council/LWSF safeguarding lead available during all data collection times so any issues can be escalated to them.
    - Participation will remain confidential, but if there is a suggestion of safeguarding issues (i.e., someone is at harm), confidentiality will be broken, and North Yorkshire County Council/LWSF and the University of Sheffield safeguarding policies will be adhered to.
- Data protection
    - All data will be securely stored and processed in line with data protection requirements.
    - All project data will be stored on the University of Sheffield secure drive, and only accessible to those within the research team members who require this.
    - Any personal data will be stored in password protected folder in the secure drive (e.g., contact information for arranging interviews, audio recordings, transcripts, LWSF programme data).

7.0 Gantt Chart / timeline

		July 2022	August 22	September 22	October 22	November 22	December 22	January 23	February 23	March 23
Protocol submission + approval		X	X							
Ethics submission + approval		X	X							
Development/refining of data collection tools (PPI)		X	X							
Fieldwork (qual)				X	X	X	X			
Quant data retrieval						X	X	X	X	
Qual data analysis					X	X	X	X	X	
Quant data analysis						X	X	X	X	
Interim feedback report							X			

Draft final report									X	X
Final report										X
Dissemination										X

8.0 Outputs

Outputs will be informed by discussion and consultation with our LWSF project partners

Proposed outputs include:

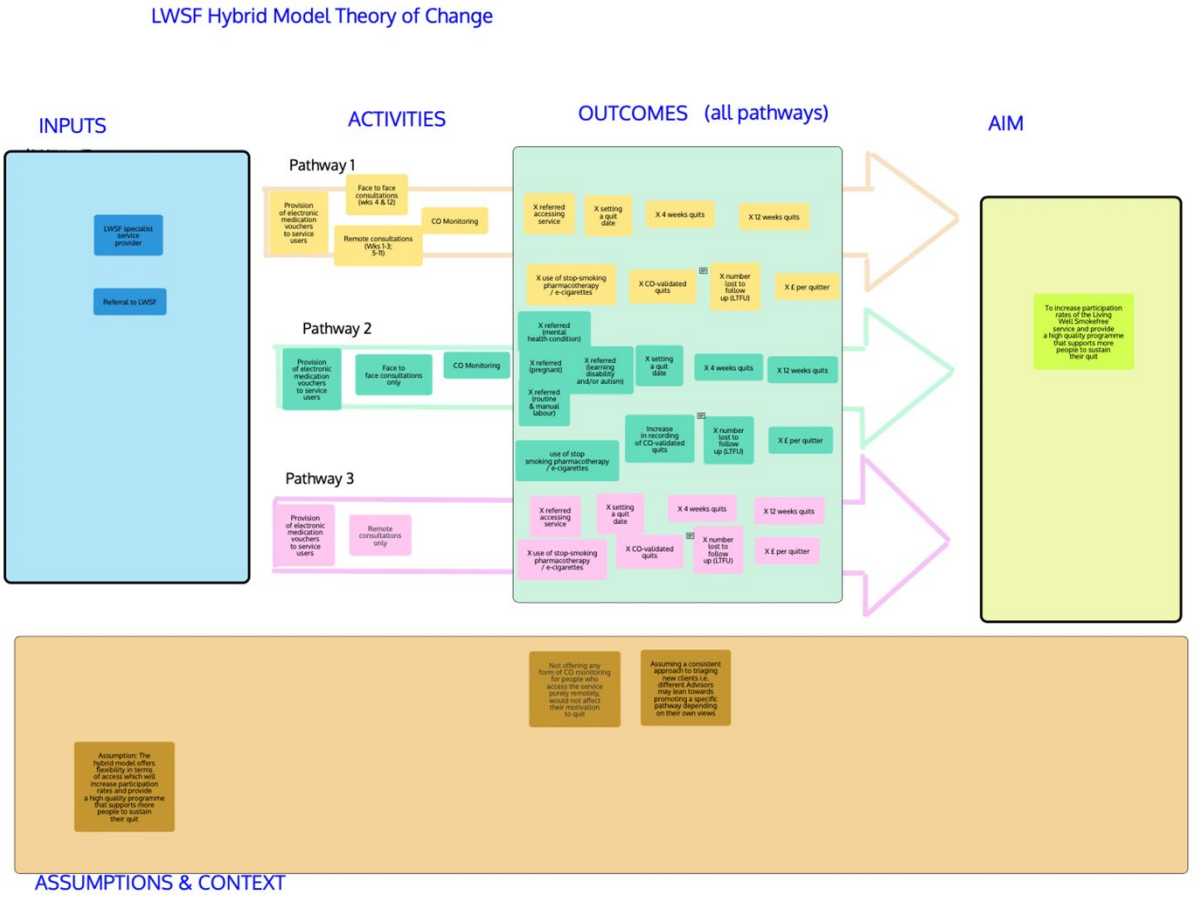
- an interim report/presentation with LWSF project partners where we discuss emerging findings and initial learning to help shape continued development of the service.
- a final research project report with a brief executive summary for our project partners and for NIHR
- public friendly summary of research and findings (potentially in the form of an infographic or animation)
- short policy/research briefing papers for policy and practice stakeholders.

We also aim to produce two academic papers, inducing:

- a descriptive protocol of our approach
- and, a mixed-methods findings paper reporting the qualitative perspectives and experiences of service staff and service users regarding the LWSF service, and descriptive statistics exploring how demand and quitting outcomes differs among routes of referral and priority client groups.

9.0 Appendix

Appendix 1: Living Well Smokefree Theory of Change



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