Clear Conversations:

Evaluating a Verbal Health Literacy intervention in Derbyshire

1. Background

1.1 Health Literacy

Health Literacy is important so that everyone has the ability to access and receive high quality healthcare (WHO 2014). Health literacy has been defined as a person's ability to understand and use information to make decisions about their health so they can 'be active partners in their care' (NHS England, 2024). People with low Health Literacy struggle to read and understand health information, communicate with health professionals, know how to act on the information they receive, and know what health services to use and when to use them (Osborne *et al.,* 2013).

1.2 Health literacy and health inequalities

There is a link between socioeconomic deprivation and low Health Literacy. That is, those with lower Health Literacy are more likely to be from socially deprived areas and have no educational qualifications (Roberts, 2015).

Low Health Literacy is associated with:

- Unhealthy lifestyles and poorer general health

- Low use of preventative services e.g. vaccinations and screening

- Increased attendance at A&E and hospital admissions

- Decreased life expectancy

(NHS 2023. NIHR, 2022, Roberts, 2015).

If Health Literacy is improved this can positively affect treatment adherence, and lead to reduced numbers of call backs, cancelled appointments and improved satisfaction and outcomes (Roberts, 2015). It has been suggested that interventions to improve Health Literacy will best be targeted at those with lower levels of

education, those living in the most deprived areas, and those with a limiting health condition or disability (Roberts, 2015).

1.3 The context of this study

1.3.1 Joined Up Care Derbyshire

Across Derby and Derbyshire three out of nine areas and six out of ten people are estimated to be below the UK average for Health Literacy and numeracy (JUCD, 2024). Joined Up Care Derbyshire (JUCD) is one of 42 Integrated Care Systems in England. It brings together NHS, local authorities, and the voluntary sector to deliver better care to whole communities, both adults and children, in Derbyshire (https://joinedupcarederbyshire.co.uk/). It aims to improve Derbyshire's population life expectancy and healthy life expectancy levels, compared to other parts of the country, and reduce health inequalities.

JUCD has a Stay Well Initiative which includes Quality Conversations, Personalisation and Health Literacy. JUCD offers free Quality Conversations training to all staff. They also provide information and training resources to staff via their website on Personalised Care and Health Literacy. JUCD appointed a Health Literacy Officer in 2022. This is a role that it is not commonly seen in Integrated Care Systems in the UK.

1.3.2 Quality Conversations

Quality Conversations is an evidenced based communications skills programme for staff, developed by the Derbyshire Psychological Insights team and Public Health Derbyshire, to support the implementation of Making Every Contact Count in Derbyshire (Pennell, 2023). It is informed by Michie et al's (2011) COM-B behaviour change model (Mitchie *et al*., 2011) and is focused on addressing health inequalities through '*compassionate and curious conversations'* (Pennell, 2023). The training sessions for staff are delivered by professional coaches and '*supplemented with a suite of localised support, web-based resources, an ambassador network and team-based sessions to embed the approach and ensure sustainably of learning'* (Pennell, 2023).

1.3.3 The Health Literacy Officer role

The Health Literacy Officer role aims to implement Health Literacy initiatives throughout the JUCD system. The officer works with organisations and teams within JUCD to support them to take evidence-based steps to provide more Health Literacy friendly services. The initial focus of the role has been on written communication. The Health Literacy Officer has supported teams to reduce the average reading age of their services' information materials from 18 years of age to 9 across 19 services. These changes have received positive feedback from both staff and patients. Now the focus is turning to how to embed Verbal Health Literacy techniques into services.

1.3.4 Verbal Health Literacy interventions - The evidence base

Improving health professionals' health literate communication skills is important and has the potential to positively impact on person centred prevention activities and healthcare, by reducing Health Literacy demands (Connell *et al*., 2023; Kaper *et al*., 2019; Murugesu *et al*., 2022). Evidence suggests that effective health conversations can potentially increase adherence to treatment, patient safety, quality of life and health outcomes (Kaper *et al*., 2019, Connell *et al*., 2023).

NHS England and Scotland both advocate the use of good communication, both spoken and written, to help address Health Literacy issues (Public Health England, 2023; NHS Scotland, 2023). In their Health Literacy toolkits and guides they recommend the use of:

- Simple language (NHS Scotland, 2023).
- Teach-back techniques (Health Education England, NHS England and Public Health England, 2023; NHS Scotland, 2023). A method of making sure patients understand the health information they receive (Yen and Leasure 2019),
- Chunk and check techniques (Health Education England, NHS England and Public Health England, 2023; NHS Scotland, 2023). Where information is broken down into smaller chunks rather than giving it all at once. Then

checking it is understood before moving onto the next ‘chunk’ (NHS Scotland 2023).

- Pictures and visual aids (NHS Scotland, 2023).

A recent study in the USA explored the patient-surgeon encounter using audio-recordings and a post encounter survey (Rainey *et al*., 2022). They found that improving communication by slowing speech, using more understandable words, and intentionally allowing more time for patients to speak and ask questions were immediately actionable ways to improve patient understanding (Rainey *et al*., 2022).

A number of studies and literature reviews have explored the use of Verbal Health Literacy techniques (Kaper *et al.,* 2019; Murugesu *et al*., 2022; Talevski *et al*., 2020; Yen & Leasure, 2019). However, there are few UK studies exploring this issue. Teach-back specifically has been shown to be effective in improving learning related outcomes. These outcomes include knowledge recall and retention and health related outcomes such as hospital re-admissions and quality of life (Talevski *et al*.,2020). The Teach-back method was recommended by 99% of those using it (Murugesu *et al*., 2022) and was considered to be quick and cost effective (Talevski *et al.,* 2020). However, there were inconsistent results related to Teach-back, with regards to knowledge retention, and implementation into routine practice was rarely considered (Talevski et al., 2020). A training session on Teach-back alone was not considered to be adequate for translation into practice to occur or be sustained (Talevski *et al*., 2020; Yen & Leasure, 2019). This indicates the need for additional implementation support. In addition, there was a lack of studies using comprehensive health literacy outcome measures (Larsen *et al*., 2022) or patient centred outcomes (Walters *et al*., 2020).

One UK qualitative study undertaken in Staffordshire focused on community pharmacy (Cork & White, 2022). Pharmacists received a one-off training session on Teach-back, chunk and check and the use of simple language and visual aids. They were given two months to use it in practice before giving their perceptions of its usefulness in a semi-structured interview. Key findings included:

- Health professionals would have preferred more time to practice the techniques with patients.
- They found chunk and check harder to use than Teach-back and felt it was better for longer rather than short consultations.
- Visual aids were useful.
- It was easy to slip back into jargon and habitual use of more complicated language.
  (Cork & White, 2022).

This highlights the need to continue to evaluate Health Literacy interventions, particularly those aimed at improving Verbal Health Literacy. It also highlights the need to explore additional implementation support, and measurement of outcomes and experiences over a longer time period.

1.3.5 The intervention to be evaluated

The intervention is a Verbal Health Literacy techniques training package for staff. Its purpose is to enable clearer health conversations. It has been developed using insights gained from the well-established Quality Conversation programme currently available to all healthcare and public health staff in Derbyshire. The Verbal Health Literacy training is a two hour interactive and experiential session. The main focus is on how staff can learn, practice and implement three key Verbal Health Literacy techniques: 'simple language', 'Teach-back' and 'chunk and check'. This is complemented with Health Literacy Officer support for implementation of the techniques into practice. The support is tailored to the individual service staff's needs.

1.3.6 The services where the intervention will be used

The intervention will be used in two very different services.

1. Live Life Better Derbyshire tier 2 weight management services (Public Health, Derbyshire County Council). The aim of the programme is to help people lose weight. The service provides online and face to face group education and advice programmes that run for one session a week over a rolling 12 week period. The programmes have an accompanying website and resources. The

programme is available for all people in Derbyshire. Eight Public Health Improvement Advisors (HIA's) offer advice to groups of up to 25 people who need to lose weight. 33 programmes run across Derbyshire, 19 online and 14 face to face. Attenders are followed up at 12, 26 and 52 weeks and a weight maintenance programme is available.

2. Derbyshire Community Health Service Pulmonary Rehabilitation programme provided within the NHS. The aim of the programme is to improve people's exercise tolerance and respiratory health. This service provides a six week rolling face to face programme that runs across 6 venues in Derbyshire. 15 members of staff, a mixture of physiotherapists, healthcare assistants and specialist nurses, offer supervised exercise and education and advice to people who are limited by their respiratory condition in Derbyshire. The physiotherapists and specialist nurses lead the sessions and have most contact with patients. Up to 12 people attend two sessions a week over the six week period which are a combination of exercise and education.

1.3.7 The proposed Theory of Change

For the Live Life Better Derbyshire service, the training will help staff to communicate in simpler language and check service users' understanding of actions they need to take. This will help service users to understand what they need to do to lose weight, be activated to self-manage their weight, take actions to lose weight, and adhere to the 12 week programme. This will help them to lose weight and maintain weight loss.

For the Pulmonary Rehabilitation service, the training will help staff communicate in simpler language and check service users' understanding of the actions they need to undertake. This is so service users will understand what they need to do to improve their exercise tolerance and respiratory health, be more likely to take actions, and thus improve their overall health. It is hoped the intervention will also help activate people to continue to manage their own physical and respiratory health beyond the programme and know what to do should they suffer an acute exacerbation.

2. Research question and aims & objectives

2.1. Research question

Can a Verbal Health Literacy training intervention for health workers improve health outcomes and reduce health inequalities for people using their services?

2.2. Aim

To investigate whether a Verbal Health Literacy training session for staff, with accompanying tailored support from a Health Literacy Officer to help implement the techniques into practice, can improve health outcomes for patients.

2.3. Objectives

a) To understand staff perceptions of the acceptability and feasibility of the Verbal Health Literacy training session, and the support to use the techniques in practice from the Health Literacy Officer.
b) To understand staff knowledge of the Verbal Health Literacy techniques and their confidence and skills to use them.
c) To understand how the Verbal Health Literacy techniques taught in the training session are being actioned in practice.
d) To determine whether subjective Health Literacy and activation skills, such as the ability to self-manage, engage with healthcare services and understand what actions to take, are improved for service users after attending programmes delivered by Verbal Health Literacy trained members of staff.
e) To measure the impact of the Verbal Health Literacy training on health and wellbeing outcomes.
f) To describe the Index of Multiple Deprivation quintile of attendees at programmes and compare with the Derbyshire population in order to assess impact on health inequalities.

3.Plan of investigation

3.1 Design

The objectives will be achieved through a mixed methods evaluation. This will consist of a process evaluation to assess acceptability, feasibility and use of the learnt techniques in practice (Moore *et al*., 2015), and a concurrent pre-test post-test measurement of outcomes, or controlled pre-test post-test measurement of outcomes where possible (Aggarwal & Ranganathan, 2019; NICE, 2012).

3.2 Timing of intervention

For both programmes staff will receive Verbal Health Literacy training and implementation support from the Health Literacy Officer. Outcomes will be measured for service users joining a programme run by trained staff. Where appropriate and for comparison, outcomes will be measured for service users joining a programme run by non-trained staff during the same period.

Half of the staff from the weight management programme (4/8) will receive the training to allow for controlled before and after comparison of outcomes. One member of staff takes a group of service users through their weight management sessions so it will be possible to identify service users linked to trained and untrained staff. This is not possible for the pulmonary rehabilitation service where different staff work with different service users throughout the programme. All six physiotherapists and two specialist nurses from the pulmonary rehabilitation service will receive the training. The focus is on physiotherapists and specialist nurses because they spend most time with service users.

3.3 Staff perceptions of the acceptability and feasibility of the training and support, and their knowledge, confidence and skills to use the techniques taught

3.3.1 Pre and post intervention questionnaires

The Health Literacy Officer collects pre and post training questionnaire data as part of their practice. This data will be made available to the research team with consent from individual staff undergoing the training. Questionnaire data will be collected,

with consent, from staff from the two participating services who receive the Verbal Health Literacy training. The Health Literacy Officer will also be training staff from other services in Derbyshire Community Health Services and the Local Authority during this time. She will be collecting the same questionnaire data from them. Therefore, we will ask these additional staff (approximately 60), who receive the Verbal Health Literacy training during the period of the study, to consent to their questionnaire data to be used in the study also. Staff will be asked to complete a short questionnaire at three time points.

1. Baseline data will be collected from staff, via a short questionnaire, prior to their attendance at the training session. The data collected at this stage will include demographic data and ascertain their current knowledge of Verbal Health Literacy techniques and whether they have had Health Literacy training in the past
2. Staff will complete a short questionnaire immediately after they have attended the Verbal Health Literacy training. This will include questions about how useful they found the training and their confidence to use the techniques taught.
3. Staff will complete a final short questionnaire 8 weeks after attending the Verbal Health Literacy training to assess their perceptions of whether they are using the techniques they learnt in their routine care provision, the facilitators and barriers faced and any support they may require helping them use the techniques in their practice.

The questionnaires will be distributed online. This will be via the Derbyshire Community Health Services NHS Foundation Trust Microsoft forms web-based package. The forms will be distributed via the Health Literacy Officer's NHS Microsoft 360 office account. The Health Literacy Officer will share the anonymised, consented data with the lead researcher via email in a password protected spreadsheet.

3.3.2 Focus group interviews

Focus groups will be used to gain deeper and richer insights into participants' experiences and views of the training session itself and the use of the techniques in practice (Kitzinger, 1995). They will allow the staff from the two participating programmes to discuss and debate each other's experiences and views (Kitzinger, 1995). They will focus on wider contextual factors such as why staff receiving and then delivering the intervention may or may not engage with it (Moore *et al*., 2015). Focus groups will supplement the questionnaires by using open rather than closed questions and encouraging more detailed responses. A topic guide will be used to facilitate the group discussion, but the researcher will be guided by the group's responses and interactions (Kitzinger, 1995) and will probe and dig deeper to understand issues of interest as appropriate (Bryman 2008).

All staff from the two participating services who receive the training will be invited to take part in the focus groups. That is four out of eight Health Intervention Workers from the weight management programme and six physiotherapists and two specialist nurses from the pulmonary rehabilitation programme. The focus groups will take place separately for each service involved. That is there will be one focus group for the weight management service staff and one focus group for the pulmonary rehabilitation staff. This will allow the two groups to discuss together the issues that are important to them specific to their area of practice. The focus groups will take place during timetabled team meeting time, so it has minimum impact on the service and staff time.

The focus groups will be carried out four – six months after attending the Verbal Health Literacy training. They will be carried out face to face or via video call depending on the services preference. Face to face will be recorded using an encrypted audio recorder and the audio files transcribed verbatim. Video call interviews will take place via Goggle Meet using the researcher's University of Sheffield Google account. The video calls will be recorded and transcribed live using the recording and transcribe functions in Google Meet. The video recording and transcripts will be downloaded from the researcher's University of Sheffield Google

drive immediately after the session and checked and saved on the University of Sheffield secure computer drive. The original recordings will be deleted from the Google drive. All the interview transcripts will be (pseudo)anonymised prior to being analysed.

3.4. Assessment of change in how staff use Verbal Health Literacy techniques in practice

To assess if there is a change in the frequency with which staff use the techniques they have learnt in practice, the lead researcher will observe or record programme sessions before and 12-16 weeks after staff have been trained. The lead researcher will observe the extent to which the Health Literacy techniques 'simple language', 'teach-back' and 'chunk and check' are used. The researcher will attend in person or ask the staff member to record programme sessions on an encrypted recorder. The researcher will use a checklist to describe how often each of the three communication techniques are used: never, sometimes, most of the time, all of the time. All staff from the two services, who will be receiving the training, will be approached for permission to assess two of their sessions (4 staff in the weight loss service and 8 staff in the pulmonary rehabilitation service). If all agree the researcher will observe 24 sessions in total. That is, twelve before they receive the training and twelve after.

Consent will be gained from all staff prior to collecting their data. The focus of this part of the project is on staff behaviour. Service users will be involved incidentally. Even so, verbal consent will also be gained from service users prior to the researcher observing programme sessions.

3.5. Assessment of individual service user health and wellbeing outcomes

The two services collect a range of data about service user outcomes. For the weight management programme service users complete routine service assessments at baseline12 and 26 weeks. For the pulmonary rehabilitation programme assessments are carried out at baseline and on completion of the programme at six weeks. That is after attendance at 8-12 sessions. This is so change can be measured over time. The researcher will seek consent to access this data for all those service users who attend either of the two participating programmes during the intervention period.

This data will be available at individual service user level if service users give informed consent. This data is stored on the services databases. Only anonymised data will be shared with the researcher.

Additional anonymised demographic data of attendees, that is routinely collected by the services, will be shared with the researcher. This data will include gender, ethnicity, age and index of multiple deprivation.

Primary and secondary outcomes for each of the two participating services will be collected. The outcomes are:

Primary outcomes

- LLBD Weight Management Programme: Weight in kilograms
- Pulmonary Rehabilitation Programme: The Chronic Respiratory Disease Questionnaire (CRDQ).

Secondary outcomes

- LLBD Weight Management Programme: The short form Warwick and Edinburgh Mental Health and Wellbeing Scale
- Pulmonary Rehabilitation Programme: Incremental shuttle walking test (in meters), Lung Information Needs Questionnaire (LINQ), Generalised Anxiety Disorder Assessment (GAD -7), Patient Health Questionnaire 9 (PHQ-9) and strength tests.

The weight management programme collects service users' weight at 0, 12 and 26 weeks. They collect the short form Warwick and Edinburgh Mental Health and Wellbeing Scale at 0 and 12 weeks.
The pulmonary rehabilitation service collects all measures at 0 and 6 weeks.
We will collect data at baseline and at the end of the programme for both services. That is:

- 0, 12 and 26 weeks (weight only) for the weight management programme.
- 0 and 6 weeks for the pulmonary rehabilitation programme.

3.6. Assessment of service users' subjective Health Literacy skills and health activation

Services users will be asked to complete an additional questionnaire as part of the research. This will be two domains of the validated Health Literacy Questionnaire (Osborne *et al*; 2013). This is to understand whether their subjective Health Literacy and health activation skills have changed after attending the programmes by Verbal Health Literacy trained or non-trained staff.

The questionnaires will be completed at the same time as the routinely collected service data, that is the secondary outcomes for each service, at baseline, 6 weeks (pulmonary rehabilitation service) and 12 weeks (weight management service). Service users will complete the questionnaire either electronically or in paper form as per the services current data collection practice. Or they will be posted to participants for them to complete and return. The mode of delivery will depend on the service's preference in order to minimise any extra burden on service staff during the research period.

Consent will be gained from all service user participants prior to collecting their data.

3.7. Assessment of changes in outcomes (at a service level)

Aggregate programme level data will be obtained from the two services for a three - six month period in 2024 when trained staff have delivered programmes and a corresponding three- six month period in 2023. This will allow comparable measurement of change over time at a service level.

For the weight management service, a control group will consist of programmes run by non-trained staff. The same aggregated data will be obtained for this control group. Individual level patient data will not be shared with researchers because not all service users will have consented to this.

The aggregate data will include:

For both services

- Attendance numbers
- Did Not Attend (DNA) numbers and programme completion rates.
- Summarised demographic data of attendees to include numbers and % by gender, ethnicity, age group and index of multiple deprivation quintile.

LLBD weight management programme

- Mean weight and standard deviation at baseline, 12 weeks and 26 weeks
- Mean weight loss and standard deviation between baseline and 12 weeks, and between baseline and 26 weeks.
- Mean score on the short form Warwick and Edinburgh Mental Health and Wellbeing Scale and standard deviation at baseline and 12 weeks.
- Mean change in the short form Warwick and Edinburgh Mental Health and Wellbeing Scale and standard deviation between baseline and 12 weeks s.

Pulmonary rehabilitation programme

- Mean CRDQ score and standard deviation at baseline and six weeks.
- Mean change in CRDQ score between baseline and six weeks.
- Mean score in incremental shuttle walking test, LINQ, GAD-7, PHQ-9 and strength test and standard deviation at baseline and six weeks.
- Mean change in incremental shuttle walking test, LINQ, GAD-7, PHQ-9 and strength test between baseline and six weeks.
- Mean change % of service users with Acute respiratory/COPD exacerbation between the same period in 2023 and 2024 (if data available).
- Mean change in % hospital attendance or admission between the same period in 2023 and 2024 (if data available).

3.8 Recruitment

We will recruit staff delivering Verbal Health Literacy training during a three month period in 2024.

We will recruit service users from two services, one within Derbyshire Community Health Services NHS Trust and one within the Local Authority. Service user recruitment is likely to take place over a six month period to recruit the minimum required sample. This is because both services run on a rolling basis. That is week 1 for one person could be week 6 for another.

We will recruit service users who enrol on the 12 week weight management programme and 6 week pulmonary rehabilitation programme after staff have (or have not) attended the Verbal Health Literacy training.

That is:

- Public Health Intervention Advisors and service users from the Live Life Better Derbyshire tier two weight management service.
- Physiotherapists, specialist nurses and service users from the Derbyshire Community Health Services (DCHS) pulmonary rehabilitation service.

Recruitment will commence once HRA and NHS ethics approval is obtained. Written informed consent will be gained for all participants in the study.

3.8.1 Inclusion and exclusion criteria

Inclusion criteria:

- Public Health Intervention Advisors delivering the tier 2 weight management programme across Derbyshire.
- Physiotherapists and specialist nurses involved in the assessment of patients and delivery of the six week DCHS NHS pulmonary rehabilitation programme.
- Adults aged 18 or over who start the rolling 12 week tier two weight management programme during the intervention period.
- Adults aged 18 or over, with Chronic Obstructive Pulmonary Disease, who are being assessed for and undertaking the six week pulmonary rehabilitation programme during the study intervention period.

- For the staff questionnaire only - Healthcare staff from other services that attend Verbal Health Literacy training, during the study period in 2024, will also be eligible.

Exclusion criteria:

- Service users attending the two service programmes outside of the data collection period.
- Other pulmonary rehabilitation staff. i.e. staff who are not physiotherapists or specialist nurses.

3.8.2 Process of recruitment

Recruitment of staff will be carried out with the advice and assistance of the service leads. The study will be presented to each of the participating services by the lead researcher prior to recruitment commencing. An email invitation will be sent to all staff that deliver the programme in the two services via the service leads in the first instance. The email will include the study's participant information sheet. This information will include the lead researcher's contact details. This is so those staff who receive the Verbal Health Literacy training can get in touch should they be interested in taking part in the observations and focus groups or if any staff wish to discuss the project further.

In addition, all staff across DCHS and DCC that receive the Verbal Health Literacy training during the period of the study will be invited to participate via the pre and post training questionnaires. Participant information will be included with the questionnaires. Staff will be able to consent to their data being used for the research at the start of the questionnaire.

All service users that are referred or self-refer into the programmes during the period of the study, after staff have (or have not) been trained, will be invited to take part. Potential service user participants will be identified and approached by a member of their direct care team in the first instance. Because both programmes are rolling programmes, this means service users start their programmes at different times. Also, both services run across a number of different venues in Derbyshire. This

means it will be very difficult for the lead researcher to obtain face to face consent from service users. For this reason a number of different options for recruitment and consent will be used.

- A link to the study information and consent form will be included in the programme enrolment email that the services send out. Potential participants will be able to read this, contact the researcher for more information if they wish, and complete the consent form electronically if they would like to take part. This information and consent form will be delivered via The University of Sheffield information governance approved online survey platform, Qualtrics (Qualtrics.com).
- Those service users who cannot or do not wish to correspond via email will be given the one page project summary information sheet by the member of staff that enrols them on the programme. The member of staff will ask the service user if their contact details can be shared with the lead researcher. The lead researcher will then contact potential service user participants by their preferred mode of contact (telephone or email) to invite them to take part. They will include the full participant information sheet with this correspondence (via email, post or verbally).
- Alternatively service users may contact the researcher themselves using the contact information on the summary information sheet.

A project information audio/video will be made available to all service users who are interested in taking part. This will be an alternative to the written information. Informed consent will be gained from all participants, electronically, over the telephone or by post in some instances where this is the participants preference. Prior to collecting or using any of their individual level data.

3.9 Sampling strategy and sample size

3.9.1. Staff

There are currently eight staff that deliver the weight management programme. There are currently six physiotherapists and two specialist nurses who deliver the

pulmonary rehabilitation programme. Four out of the eight weight management programme staff will receive the Verbal Health Literacy training. Six physiotherapists and two specialist nurses from the pulmonary rehabilitation programme will receive the training. All staff from the two participating services who receive the training, n=12, and from the wider services who complete the training during the study period, will be asked to complete the three questionnaires.

All trained staff, from each of the two services (n=12) where possible, will be observed pre and post the intervention and be part of the focus groups.

3.9.2. Service users' individual outcomes

LLBD Weight Management Programme

Between 15-25 people attend each 12 week rolling LLBD weight management programme. 33 programmes are likely to be ongoing between the three month study period in 2024, with a minimum and maximum of 495 and 825 service users joining in total. All service users starting the programmes during the period of the study will be invited to take part when they sign up. We estimate there will be approximately 660 attendees to the LLBD weight management programme. With a response rate of 50% to our request to participate in the evaluation, we expect there to be weight, health and wellbeing and Health Literacy scores at three time points for approximately 330 service users. Approximately 160 service users will be in groups led by trained and 160 in groups led by untrained staff. We expect to see a reduction in weight, an improvement in clinical outcomes and an improvement in wellbeing between baseline and 12 weeks and baseline and 26 weeks for both groups. We expect the changes to be larger in the trained group versus the untrained group. We expect there to be an improvement in Health Literacy domain scores between baseline and 12 weeks (the end of the program) for the trained group and no change for the untrained group.

DCHS Pulmonary Rehabilitation Programme

Between 8-12 people attend the six week rolling programme across 6 venues. If we do two cohorts, there will be a minimum of 96 and a maximum of 144 service users

joining the programme between the three month study period in 2024, and who will be invited to take part. With a response rate of 50% to our request to participate in the evaluation, we expect there to be clinical, health and wellbeing and Health Literacy scores at two points of time for approximately 72 service users. We expect to see improvement in the CRDQ and other secondary outcomes after attending the programme. We expect there to be an improvement in Health Literacy domain scores between baseline and 6 weeks after the end of the programme.

3.9.3 Outcomes at a service level

For the aggregate outcomes for each service, we will use summarised data only.

LLBD Weight Management Programme sample size calculation

From January to March 2023 the mean starting weight was 103.68kg. The mean weight on completion of the 12 week course was 99.60kg. So, the mean weight loss was 4.08 kg for this cohort. This was larger than the mean weight loss of 2.3 kg for behavioural weight management interventions in primary care at 12 months compared with controls (Madigan *et al*, 2022). But people can gain weight after initial loss so we are happy to use the historical Derbyshire data to help calculate a required sample size.

We expect the mean weight loss for the Derbyshire service to be larger in 2024 than in early 2023 potentially due to the health literacy training but also likely to be related to improvements management have made to the service between 2023 and 2024. We would expect a minimum of a 10% increase in the mean weight loss in the trained group vs. untrained group at 12 weeks, that is, 4.7kg vs. 4.3kg. With an estimated pooled standard deviation of 1.6, a sample size of 252 would be required in each group to detect this size of difference with 80% power at a 5% level of significance. As stated earlier there will be approximately 330 service users in each group who can be invited to take part. We therefore should be able to recruit sufficient numbers (252) to ensure we will be able to detect an improvement in weight loss over time at a service level.

We would expect the increase in the mean CRDQ score at 6 weeks in 2024 (post training) to be larger than the increase in the mean CRDQ score in 2023 (pre training). We are unlikely to have statistical power to detect small differences based on numbers of service users if we limit the 'post' time period to the three month study period in 2024 and the corresponding 'pre' time period in 2023. We need to extend this request for data to cover a six month period.

3.10 Data analysis

The study will produce both qualitative data and quantitative data. The analysis of the different types and sets of data will occur separately.

3.10.1 Qualitative data

The qualitative data will be analysed based upon Framework analysis (Ritchie & Lewis, 2003). Analysis will follow the four stages of this approach: familiarisation, identification of a thematic framework, charting, and then mapping and theorising. A spreadsheet or code book will be used to organise and compare and contrast the data (Richie & Lewis 2003). NVIVO 12, an electronic qualitative data management tool, will be used to store and organise the data.

3.10.2 Observations

There will be 24 completed checklists for 12 members of staff observed before and after the training. For each health literacy technique, a 2x2 table will be created. This is so we can compare the % of Verbal Health Literacy technique used, most/all of the time versus sometimes/never, pre training and post training. We will make this comparison using McNemar's Test.

3.10.3 Quantitative staff data

The three staff questionnaires will be analysed separately because they each ask a different set of questions. Analysis will be descriptive e.g. showing the percentage staff finding the training helpful or not, and using it in practice or not. We will also test relationships between variables from different time periods. In particular we will give

each staff member a unique ID and compare their experiences after the training and two months later to see if staff who found the training helpful report that have been able to continue to use the techniques. We are undertaking this analysis on all staff receiving training from any service, not just the 12 staff from the weight management and pulmonary rehabilitation services.

3.10.4 Individual service user outcome data

LLBD Weight Management Programme

For the individual level outcome data, the analysis will be descriptive, displaying mean weight loss, mean short form Warwick Edinburgh score, and mean scores for the Health Literacy Questionnaire domains at the three time points. Then multiple regression will be used to test differences in changes in means between baseline and 12 weeks in the trained and untrained groups. We will also consider whether people who had an improvement in the Health Literacy Questionnaire domains were more likely to have better outcomes.

DCHS Pulmonary Rehabilitation Programme

For the individual level outcome data, the analysis will be descriptive, displaying mean CRDQ score, incremental shuttle walking test, LINK, GAD, PHQ-9 and strength test scores. Then multiple regression will be used to test for changes in means between baseline and six weeks. We will also consider whether people who had an improvement in the Health Literacy Questionnaire domains were more likely to have better CRDQ scores.

3.10.5 Aggregate service data

For the aggregated outcome data we will compare mean change in an outcome in a three month period before the training and in the three month period after the training for trained and untrained groups. Means and standard deviations will be provided by the services, that is, no individual data will be shared with researchers.

To meet the final objective, we will compare the IMD quintiles for attendees at the programmes in the three month period post-training with the IMD quintiles for the

Derbyshire population. The expectation is that the % of people in socially deprived quintiles will be higher for the programmes than for the Derbyshire population.

SPSS and Excel spreadsheets will be used to store, organise and assist in analysis of the quantitative data from multiple sources.

4. Ethics

Important ethical considerations for this mixed methods study include:

Informed Consent- Informed consent will be gained from all participants prior to their involvement [or their individual data being used]. This will ensure they have a clear understanding of what the research project is and what it is hoping to achieve through their involvement. Gaining informed consent will ensure participants understand and are happy with their role in the research. It will also make sure they understand what will be done with the data that will be collected from them. Participant information sheets will be made available to all interested participants. They will have ample opportunity to read this and talk through any queries with the Lead Researcher prior to agreeing to participate. They will then sign a consent form immediately prior to being observed/recorded/completing outcome measure questionnaires/giving access to their clinical details /being interviewed. There will be separate consent forms for the different data collection methods. Participants will be informed that their participation is voluntary and that they can withdraw at any time if they wish.

Low Literacy/English as a second language- It is likely that some of the service-users invited to participate in the study will have low literacy skills or English as a second language. In order to address this, study materials will be written in plain English and designed in conjunction with the Health Literacy Officer and the project partnership group. A project information video will also be made available. When taking consent the Lead Researcher will go through each point with participants individually and summarise in plain language.

Coercion and Inconvenience – Recruitment to research projects is difficult especially when recruiting busy healthcare/public health workers working in time

pressured and target driven environments. Participants will not be made to feel under any pressure to participate and their participation should be voluntary.

Maintaining confidentiality- This study will involve collecting a range of staff and patient data including clinical data. Confidentiality will therefore be extremely important and will be maintained throughout the study. All data collected will be anonymised/pseudonymised. The relevant information governance and information security procedures will be followed pertaining to the specific types of data that will be accessed and or generated.

5. Data management

A data management plan will be completed to ensure the appropriate information governance practices are followed according to NHS, local government and University policies. Confidentiality and data sharing agreements will be put in place where appropriate, to ensure data from the NHS and local authority services is shared safely and securely between them and the University research team.

6.Timescales

(Ethics outcome dependent)-

June- July 2024 - Recruitment of staff participants and pre intervention staff observations.

July- August 2024 - Delivery of training package and pre and immediately post intervention staff questionnaires.

July – November 2024 – Recruitment of service users and baseline outcome measures and Health Literacy Questionnaire data collection.

August– February 2025 – Service user post intervention outcome measures and Health Literacy Questionnaire data collection.

September – October 2024 – Two month follow up staff questionnaires.

October – November 2024 – Post intervention staff observations and/or recording of consultations.

November - January 2025 – Staff focus group interviews.

August 2024– March 2025 - Data analysis.

January – March 2025 – Write report/disseminate.

7. Patient and Public Involvement and Engagement

A project partnership (advisory) group, including staff, patients and the public from the participating services as well as wider services within Derbyshire Community Health Services and Derbyshire County Council will provide advice and recommendations regarding recruitment, analysis and interpretation. They have helped to develop easy read versions of documents e.g. the participant information. Their knowledge and experience will be utilised to inform decision making and analysis. They will be key in ensuring the results of the study are presented in a way that is meaningful and easy to understand to a wider audience not just academics and NHS and Local Authority managers.

8.Dissemination and impact

An event will take place at the end of the study to present the findings to Derbyshire Community Health Services and Derbyshire County Council.

A final report will be written and circulated to Derbyshire Community Health Services and Derbyshire County Council. An easy read summary of the report will also be produced.

The outcomes of the research, positive or negative, will be disseminated in a peer reviewed publication and presented at a national conference. NHS and Local Authority communication networks for Trusts and Commissioners will be used to ensure the findings reach appropriate audiences. If there is no change in patient outcomes the focus of dissemination will be on why outcomes did not improve and describe how the programs might be improved to increase their chance of impacting on patient outcomes in the future. This will help commissioners and service providers to gauge the value of Verbal Health Literacy training programs and make decisions about funding and future content of programs.

9.Expertise of the researcher and associated team

Dr Cheryl Grindell will lead the research and is a Research Associate at the University of Sheffield. Cheryl Grindell is a mixed methods researcher with experience of working closely with health services to develop and evaluate interventions. Professor Alicia O'Cathain will offer senior oversight for the project. She is Director of the Health and Care Research Unit at the University of Sheffield. She is a mixed methods researcher and statistician who had led numerous evaluations of health service interventions. Laura Walton-Taylor is a Psychologist and Health Literacy Officer for Joined up Care Derbyshire, Jane Hawley is a Healthcare Public Health Practitioner, Derbyshire County Council and Dr Jo Hall is Derbyshire Psychological Insights team lead. These team members will offer expertise in the intervention and needs of the Integrated System.

10.Project management

The University of Sheffield will have overall responsibility for the study along with the research lead. The study will be registered with the local Research & Development and Knowledge and Innovation departments. The research team will meet monthly to progress the study.

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