# NIHR Bristol and Cardiff PHIRST

## The evaluation of the Scottish Borders/Food Train Eat Well Age Well implementation of the Patient Association Nutrition Checklist (NIHR135412)

## V2.0 27/09/2022

**Version Control Table**

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version.

| Amendment No. | Protocol version no. | Date issued | Summary of changes made since previous version |
|---|---|---|---|
| 1 | 2.0 | 27/09/2022 | • Due to low numbers of older adults receiving the intervention and being identified as at-risk of malnutrition (the eligibility criteria for recruitment to the study), the planned data collection with older adults has been removed from the protocol.<br>• As a result of the above, objectives 1-3 have been removed from the previous version of the protocol, and research questions 1-4 likewise been removed. Older adults as a participant group have been removed from the protocol.<br>• An online survey for use with implementers and staff at service provider partners has been added as a supplement to conducting interviews, where interview participation is not feasible. |
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## Background

Malnutrition has been shown to affect over 1.3 million older people (over the age of 65) in the UK and this figure may be worse following the COVID-19 pandemic. Malnutrition has adverse effects on health and wellbeing outcomes, including increased risk of hospitalisation. Furthermore, the levels of malnutrition in the community are largely undetected and untreated. Early identification of older people, living in the community, who may be at risk of malnutrition, and subsequent treatment, can improve outcomes for these individuals.

The Patient's Association Nutrition Checklist (referred to as the "Checklist") is a simple, cheap tool that can be used by staff working with older adults in the community, across various sectors, to identify older adults at risk of malnutrition. The Checklist is being rolled out by various service provider partners (including social care, housing and voluntary sectors) in the Scottish borders, coordinated by the FoodTrain Charity's Eat well Age Well project. Cardiff University, as part of the Bristol and Cardiff Public Health Intervention Responsive Studies Team have been allocated as the evaluation team for the project by the National Institute of Health Research.

The aim of the evaluation is to understand whether using the Checklist is:

1. feasible in this setting; and
2. beneficial for older adults themselves, the staff completing the Checklist and the service provider organisations.

This will be done by collecting and analysing organisational questionnaire data from the service provider partners, organisational data routinely collected by Eat Well Age Well and interview data from staff in the service provider partners and trainers in Eat Well Age Well. This information will then assist with potential further roll-out of the Checklist in Scotland and the UK.

## Key evaluation aims and objectives.

The primary aims of the evaluation are to:

i. understand and evaluate the perceived impact of the Patients Association Nutrition Checklist (referred to as 'The Checklist') for older adults, implementers (staff completing the Checklist with older adults) and service provider partners that the implementers work/volunteer for; and
ii. assess the feasibility of initial roll-out of the Checklist to support and inform the future implementation and strategic inclusion in a broader geographical area and nationally.

The objectives of the evaluation are:

1. to explore the barriers and facilitators of implementation of the initiative from the perspectives of implementers (staff completing the Checklist) and service provider partners (social care, housing and voluntary sector).
2. to evaluate the feasibility of implementation of the initiative in different service provider partner contexts.
3. to explore the mechanisms of action through which the initiative may or may not achieve its outcomes in order to refine the intervention Logic Model.
4. To assess the feasibility of collecting unit cost data from Eat Well Age Well required for health economic evaluation in a potential future evaluation.to assess the availability of NHS routinely-collected data on relevant outcomes
5. to develop a report with recommendations for future working and to inform wider rollout, integrating with current systems.
6. to develop a dissemination plan and communicate findings to range of stakeholders including service users, service providers, commissioners and policymakers.

The research questions are:

1. Is implementation of the Checklist feasible and acceptable to staff and the older adults they work with in different service provider partner contexts?
2. Is the study design and collection of qualitative data and quantitative outcome measures from older adults feasible in this setting?
3. What NHS routinely collected data could be utilised in a future evaluation?

## Co-production and PPIE activity

The intervention being evaluated was developed by a collaboration between public and practitioner stakeholders and academics. The Patients Association Nutrition Checklist was developed by the Patients Association and subsequently modified in partnership with the Wessex Academic Health Science Network (Wessex AHSN), Bournemouth University and the Managing Adult Malnutrition Pathway (1). The Checklist has been piloted across a number of health, social care and voluntary settings including GP practices, domiciliary care, Hampshire Fire and Rescue Service and Age UK, all of which provided positive feedback on the acceptability of its use and perceived effectiveness.
This evaluation protocol has been co-produced via a collaborative Task and Finish Group (TFG) process. The protocol development process involved shared decision making between relevant stakeholders in the TFG including representatives from Eat Well Age Well (Food Train), NHS Borders, Scottish Borders Council, The Patients Association, the University of Glasgow and Bournemouth University, who provided expert knowledge and experience of the intervention, the delivery partners and the Scottish Borders context. Due to the number of stakeholders involved in the Task and Finish Group, a sub-group of key stakeholders was identified in the first meeting of the Task and Finish Group which met more regularly to develop the intervention logic model (see Appendix 1) and protocol drafts and fed into the wider TFG to consult and agree on key development points. Representatives of the Eat Well Age Well project, who coordinate the delivery of the Checklist in Scottish Borders, have been fully involved in the protocol writing sub-group of the TFG, along with a representative from NHS Borders and Scottish Borders Council. Key relationships developed between the PHIRST project team and TFG members during regular and continued contact during this process will form the foundations of the Project Management Group (PMG).
Following initial development in the TFG sub-group, the Logic Model was finalised in consultation with all stakeholders of the Task and Finish Group and was then used to refine the final project objectives. Working with the methods outlined in the original proposal from Eat Well Age Well, the PHIRST research team at Cardiff University have worked in collaboration with Eat Well Age Well and in consultation with wider stakeholders in the Task and Finish Group to refine the proposed evaluation methods and develop the protocol. Public and practitioner involvement in the protocol development has been undertaken following a variety of methods. The team consulted with the initiative's Delivery Group who advised on appropriate methodology for participant identification, recruitment and data collection processes. One to one consultation with public representatives, recruited from NIHR's People in Research initiative has ensured that all participant facing documents have been collaboratively produced with members of the public, including data collection materials and outcome measures.

Ongoing and meaningful public involvement throughout the project has been considered with the TFG and guided by the public involvement representatives. Ongoing public involvement representation (potentially from public representatives who contributed to the TFG process, the Patients Association, Borders Older Peoples Planning Partnership (BOPPP) and/or representation from a service provider partner already implementing the initiative) will include collaborative decision making with the PTM into project design, all participant-facing materials, project reports and dissemination materials. Following consultation with public involvement representatives, co-production within the project will include focused public involvement meetings with public representatives, as well as membership of public involvement representatives at PTMs, to ensure shared decision making at project management level. In addition, the project team will support opportunities for development for all public representative team members.  Participant questionnaires and interview topic guides will be developed in collaboration with public and practice stakeholders and also piloted with public representatives prior to use. The project will address malnutrition (as under-nutrition) in older adults, a potentially sensitive topic area for some participants; the project team will be guided by the public representatives during all co-production work on how to minimise any negative impacts of the project.

**Governance**

The project team will include the PHIRST team members and stakeholder members involved in the identification of potential participants and will meet at least fortnightly. A wider Project Management Group [PMG], with representation from key stakeholders and the public, will meet at least 3 times at key stages of the project.

**Project design and setting**

The study will utilise a mixed-method design, incorporating observational and process evaluation of the initiative, comprising: 1. quantitative data collection in the form of participant online surveys and operational data from service provider partners and Eat Well Age Well; and 2. qualitative data collection in the form of participant interviews with implementers (staff who complete the Checklist as part of their job role) and service provider partners.
Delivery of the initiative by Eat Well Age Well in community settings across Scottish Borders social care, housing and voluntary sectors began in September 2021, following successful engagement with stakeholders. Implementer/ service provider partner staff participants will be identified by Eat Well Age Well and the service provider partners respectively.

**Participants**

Participants will include:

1. Implementers (staff who are in contact with older adults as part of their job role and complete the checklist with them); and
2. Staff at service provider partners where implementers work/volunteer.

See Table 1 for inclusion/ exclusion criteria.

Table 1: Participant inclusion and exclusion criteria

| Participants | Inclusion criteria | Exclusion critera |
|---|---|---|
| **Implementers** | • Aged ≥18 years old<br>• Staff/volunteer at a service provider partner completing the Checklist with older adults as part of their job/volunteer role. | |
| **Main contact in service provider partners** | • Aged ≥18 years old<br>• Relevant managerial position in a service provider partner | |
| **Staff at service provider partners** | • Aged ≥18 years old<br>• Staff at a service provider partner responsible for delivering/ overseeing/supporting the implementation of the Checklist.<br>OR | |

| | | |
|---|---|---|
| | • Staff at a service provider partner responsible for the management of staff completing the Checklist. | |
| **Eat Well Age Well trainers** | • Aged ≥18 years old<br>• Staff at Eat Well Age Well who train implementers to use the Checklist | |

**Participant identification and consent**

Service provider partner operational data
Consent for the collection of operational data regarding implementation of the Checklist from service provider partners will be collected at the service provider partner level. At recruitment stage of service provider partners, EWAW research team members will identify a main contact/s (of an appropriate managerial position) in the service provider partner and provide them with an Information Sheet. They will be asked to sign a consent form (either on paper copies to be returned to Cardiff University by post or by completing the form online via Qualtrics). To ensure transparency, a statement detailing the data sharing process will be included on the Implementers Participant Information Sheet and during Implementer training.

Implementers
At EWAW-organised Checklist training sessions, Implementers' will be provided with a Participant Information Sheet by the EWAW-trainer or PHIRST researcher. The EWAW-trainer will explain the evaluation in detail and ask Implementers to complete a contact form (including name, address, telephone number, email) and sign a project consent form (either on paper copies to be returned to Cardiff University by post or by completing online via Qualtrics).
The main contact at service provider partners will be asked to distribute an invite to relevant staff in the service provider organisation to take part in a qualitative interview; staff will be asked to contact the project team directly by telephone or email if they are interested in participating.

For qualitative interviews, the project team will contact implementers and staff at service provider partners to provide the project Participant Information Sheet by post or email. The participant will be given sufficient time to consider the information and if happy to take part. Informed consent will be taken verbally over the telephone or videoconferencing using the consent script. The verbal consent process will be audio recorded and a paper consent form will be completed and signed by the researcher on behalf of the participant.
All participants completing an interview will be offered a £20 voucher when they complete the interview. Participation in all interviews will be voluntary, arranged at a convenient time and via telephone or videoconferencing depending on the participant's preference.

**Project data**

Due to where the initiative is being implemented and the study team are located, remote study data collection for survey data and all qualitative interview data is required. Qualitative data will be collected by telephone or video-conferencing (via zoom or Microsoft teams). For online quantitative data collection, an accessible data collection platform (via Qualtrics) will be utilised to allow data to be collected on laptops, tablets or phones as required.

Qualitative data collection

Qualitative interviews will be conducted with the following research participants: 1. Implementers (staff completing the Checklist); and 2. Relevant staff at service provider partners (managers/ line managers of implementers).

*Implementers (staff completing the Checklist)*

Participant interviews will explore the barriers and facilitators of implementation of the initiative and research from the perspectives of implementers. These interviews will explore: 1. the views of the participants regarding training provided, incorporation of the initiative into their existing job/volunteer role and ongoing support and supervision required for implementation; 2. the views of the participants regarding completion of the Checklist and delivery of the initiative; 3. perceived impact of the initiative on short-term outcomes, as described by the initiative's Logic Model (e.g. increased screening of potentially at risk older adults, likelihood of older adults accessing support services etc); 4. the views of the participants regarding provision of evaluation information and feasibility of outcome measures; 5. Usual practice/ fit with other practice and services; and 6. Impact of COVID-19 on provision of services. Approximately up to 15 Implementers will be interviewed (see Analysis section for sample size calculation). Interviews will be designed to last up to 45 minutes. Sampling will be purposive and will ensure a spread across service provider partner.

Relevant staff at service provider partners (managers/ line managers of implementers)

To explore the barriers and facilitators of implementation of the initiative and research from the perspectives of relevant staff (Management/ line managers) in service provider partners. These interviews will explore: 1. barriers and facilitators to incorporating the initiative in the context of the service provider partner; 2. provision of ongoing support and supervision for implementation; 3.usual practice/ fit with other services; 4. the views of the participant regarding collation of organisational implementation data; 5. plans/ requirements/changes made to organisational practices for potential integration or future rollout of the initiative; 6. Cost of implementing the initiative at organisational level, and 7. Impact of COVID-19 on provision of services. All relevant staff at service provider partners will be invited to interview. Interviews will be designed to last up to 45 minutes. Sampling will be purposive and will ensure a spread across service provider partners.

Survey data with implementers and staff at service provider partners

To supplement qualitative interview data with implementers and relevant staff at service provider partners (managers/ line managers of implementers), and to have broader reach of the data collected, online surveys will be emailed to implementers and relevant staff at service provider partners. Managers at service provider partners will be asked to distribute the survey with implementers within the organisation. The survey will explore: 1. the views of the participants regarding training provided, incorporation of the initiative into their existing job/volunteer role and ongoing support and supervision required for implementation; 2. barriers and facilitators to incorporating the initiative in the context of the service provider partner; 3.usual practice/ fit with other services; 4. plans/ requirements/changes made to organisational practices for potential integration or future rollout of the initiative; and 5. Impact of COVID-19 on provision of services.

Other data

*Training evaluation data*

Pre- and post-training data, routinely collected by EWAW, will enable measurement of the impact of the Checklist training on Implementers' knowledge of dietary needs, confidence in identification of malnutrition risk in older adults, knowledge of available signposting to malnutrition support for older adults, knowledge of the availability of malnutrition screening tools and confidence to use the Checklist in existing job role.

*Health economics*
In order to assess the feasibility of collecting data required for a health economics evaluation, identification and collection of unit costs for resource inputs will be conducted in collaboration with the delivery team and the service provider partners.

*Operational data*
Descriptive anonymous operational data collected by service partner partners will be collected including reporting numbers of people screened in age categories, number of older adults identified at risk of undernutrition/ in need of nutritional support, numbers of older adults signposted to dietary advice from a dietician, referred to GP, dentist or community services and numbers accessing malnutrition advice line (ref). Data will be provided per month and at organisational level. Identification of sources of population/ local level and individual-level NHS routinely collected data.

**Data management plan**

Cardiff University will be the data controller for this evaluation. The project will generate the following data:

1. participant consent and contact details (implementers and staff at service provider partners);
2. verbal consent (and associated researcher-completed paper consent) for all qualitative interview participants;
3. operational data, unit costs data and pre- and post-training data collated by EWAW; and
4. qualitative project data in the form of qualitative interview recordings and transcripts.
5. Quantitative and qualitative data in the form of online surveys.

Consent forms (Implementers and main contact in service provider organisations) will be completed via a secure Cardiff University-approved online platform (Qualtrics) and therefore returned directly to the project team at Cardiff University.

All potential participant names and contact details will be entered onto a password-protected Project Management database (MS Access) stored on secure Cardiff University servers and participants will be allocated a unique pseudonymised participant identification number (PID). Verbal consent will be recorded using encrypted digital Dictaphones. Audio files from participant consent will be uploaded to an access-restricted folder on secure Cardiff University servers and stored using unique PIDs. Contact details will be collected over the telephone and immediately entered on to the Project Management Database. Project data will not be stored along with the participant names and contact details.

**Operational data** will be collected by Eat Well Age Well from service provider partners on a monthly basis, at implementer and service provider partner level. Anonymised operational data and unit cost data will be transferred securely using Fastfile to Cardiff University from Eat Well Age Well, subject to a Data Sharing Agreement. All organisational implementation data will be transferred in pseudonymised form at service provider partner level (linked using a unique site identification number). Service provider partner identifiable information will be sent separately from project data.

**Qualitative data** will be generated in the form of interview audio files, transcripts and observation notes. Online qualitative interviews and telephone interviews will be audio recorded using an encrypted external Dictaphone Audio files from interviews will be uploaded to an access-restricted folder on secure Cardiff University servers, as soon as is reasonably possible following an interview. Once uploaded, they will be securely deleted from recorders. Transcription will be undertaken either by Cardiff University administrators or by an external transcription company which have been approved to process data according to our anonymisation instructions and confidentiality agreement, recordings will be sent via secure file transfer for transcription. All identifiable information will be removed at the transcription stage and transcripts will be pseudonymised using unique participant identification numbers.

**Online survey data** will be generated in the form of online surveys and collected via a secure, Cardiff-University approved platform (Qualtrics). Responses will be downloaded for analysis (see below) as an excel file and stored securely.

No data will be stored on laptops but instead accessed via the University secure remote desktop. All data will be stored, as per Cardiff University and University of Bristol guidelines, for 10 years. A detailed data management plan will be developed by the project team prior to data collection.

## Analysis

Audio-recorded interviews will be transcribed fully, and anonymised for analysis. Sufficient interviews will be conducted to achieve "information power"(Malterud et al 2016 (8)) which focuses on the quantity and quality of information gathered relevant to the research question rather than sample size, but is likely to include approximately up to 15 older adults, with similar numbers of implementers and staff from service provider partners. Computer software (NVivo v12) will be used to manage the qualitative data and transcripts. Thematic analysis, as outlined by Braun and Clarke (9) will be used to analyse each of the sub-sets of interviews (older adults, implementers and service provider partners) separately and independently. Two qualitative researchers will develop an inductive thematic framework, grounded in the data, which will categorise themes and subthemes. The thematic framework will be used to code each subset of interviews, with 20% of the interview transcripts double coded to ensure reliability. A qualitative synthesis across the older adults interviews will provide an over-arching synthesis of older adults' and their families experiences of the implementation of the initiative and its perceived impacts.
Online survey data from implementers and staff and service provider partners will be in the form of quantitative and qualitative data and will be analysed accordingly.
All quantitative will be descriptive in nature.
Continuous data will be reported as means and standard deviations, or medians and interquartile ranges, as appropriate. Categorical data will be reported as frequencies and proportions. Analysis of pre- and post-training data will similarly be descriptive in nature. All data will be reported as pre- and post- for training data and initial data and follow-up for questionnaire data.

No formal economic analysis will take place. However, unit costs for resource inputs will be identified and collected, and summarised. The use of routinely collected data sources to measure resource use will also be considered. Operational data collected by partner organisations will be descriptively analysed.

A triangulation exercise will be conducted combining all of the qualitative results with the quantitative data analysis results including an assessment of potential barriers and facilitating factors (gathered from all data sources) that may need to be taken into account for the implementation plan, including recruitment strategies, intervention mechanisms and their interaction with local context.

A statistical analysis plan will be written prior to analysis.

## Ethics and Governance

The study will be registered with the research governance team at Cardiff University. The study will also apply for approval from Cardiff University's School of Social Sciences Research Ethics Committee. Approval will be obtained from the service provider organisation (through consent of the main contact within the organisation) who will consider local governance requirements and site feasibility. Ethical and governance approvals will be obtained before recruitment of participants within the service provider partner.

## Risk assessment

A risk assessment for the project will be developed and regularly reviewed by the project team; risks associated with project design, data management and analysis and staffing will be considered and mitigated. The study has been designed to reduce face-to-face contact with study participants due to the relative locations of the project team and delivery of the initiative. No addition contacts with implementers or older adults, above usual practice, is required and this will satisfy safety requirements due to the ongoing COVID-19 pandemic.

## Timeline and Milestones

- Month 1 (Jan 2022): Proposal submission to NIHR
- Month 1 (Jan 2022): Ethical approval received
- Months 1 and 2 (Jan and Feb 2022): Data base development and testing
- Months 1-5 (Jan-May 2022): Service provider partner recruitment
- Months 2-5 (Feb-May 2022) Training of the EWAW trainers and implementers
- Months 2-9 (Feb-Sept 2022): Operational and unit cost data collection
- Months 3-7 (March-July 2022): Assessment of feasibility of recruiting older adults
- Months 3-10 (Mar-Oct 2022): Qualitative interviews with all stakeholders
- Months 2-10 (Mar-Oct 2022): Quantitative data entry and cleaning
- Months 10-11 (Oct-Nov 2022): Quantitative data analysis
- Months 9-11 (Sept-Nov 2022): Qualitative data analysis
- Months 11-12 (Nov-Jan 2023): Data triangulation, refining logic model, writing of report / implementation recommendations / dissemination materials
- Post project: Dissemination to wider stakeholders

## Outputs

Project outputs will include an implementation package stakeholder report, incorporating relevant findings from the project and detailing recommendations of how to deliver the initiative to inform wider rollout in different service provider partner contexts. Final results will be published in an academic paper, or other report format, as agreed by the research team and wider stakeholder group. Dissemination materials will be developed for all stakeholders including participants and service provider partners. The most appropriate and accessible format for dissemination materials will be determined following consideration with stakeholders and will be a component of the project's co-production activity. The project team will also consult with Eat Well Age Well and other relevant stakeholders including Malnutrition Task Force and Age UK to disseminate project findings via social media and websites and at a strategic level to Scottish Government and/ or Public Health Scotland via relevant reports or presentations at local/ national meetings. Peer-reviewed academic papers and presentations at academic and professional meetings will be pre-determined in a publication policy.

## References

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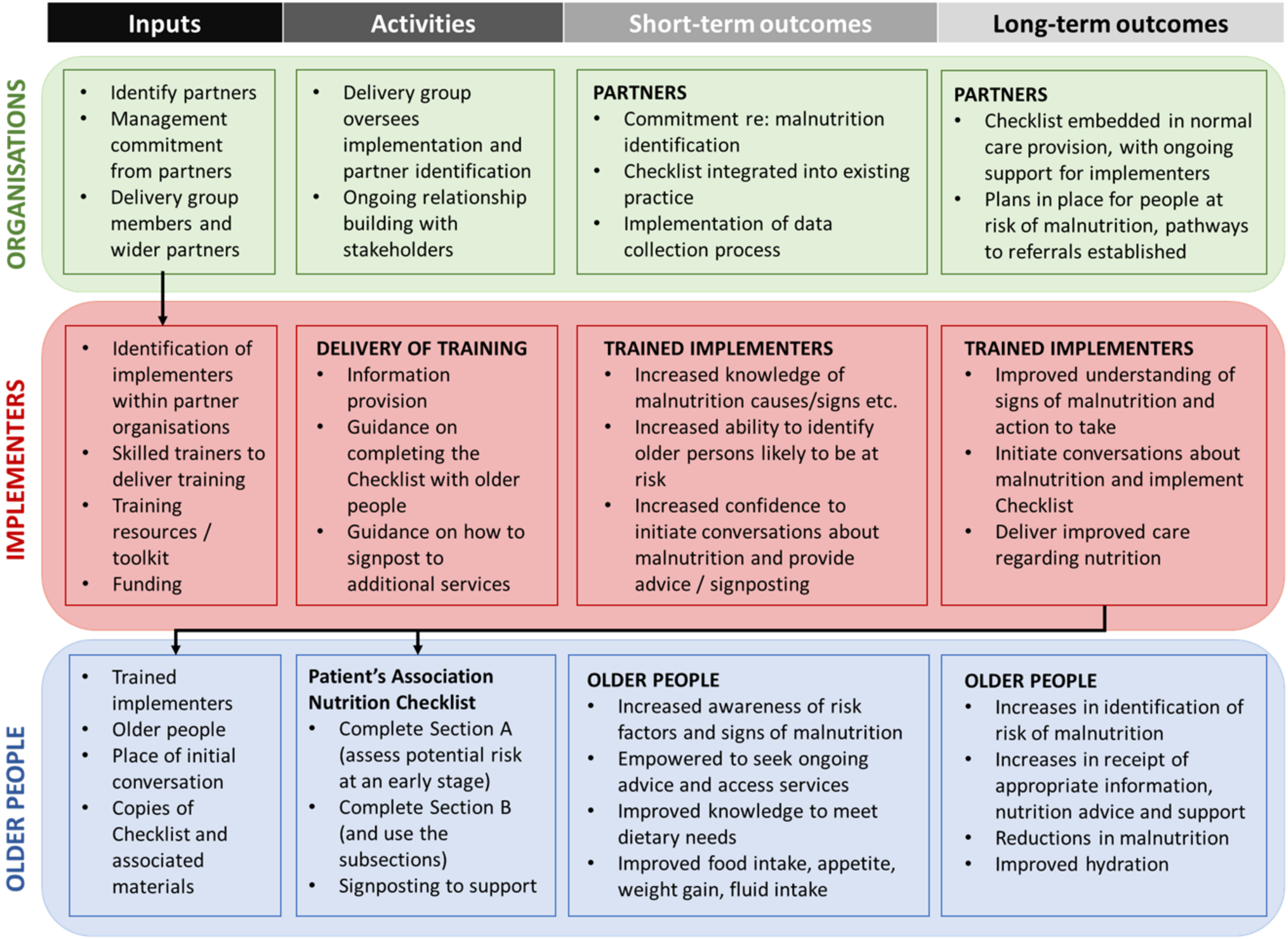
## Appendix 1. The intervention logic model



| | Inputs | Activities | Short-term outcomes | Long-term outcomes |
|---|---|---|---|---|
| **ORGANISATIONS** | • Identify partners<br>• Management commitment from partners<br>• Delivery group members and wider partners | • Delivery group oversees implementation and partner identification<br>• Ongoing relationship building with stakeholders | **PARTNERS**<br>• Commitment re: malnutrition identification<br>• Checklist integrated into existing practice<br>• Implementation of data collection process | **PARTNERS**<br>• Checklist embedded in normal care provision, with ongoing support for implementers<br>• Plans in place for people at risk of malnutrition, pathways to referrals established |
| **IMPLEMENTERS** | • Identification of implementers within partner organisations<br>• Skilled trainers to deliver training<br>• Training resources / toolkit<br>• Funding | **DELIVERY OF TRAINING**<br>• Information provision<br>• Guidance on completing the Checklist with older people<br>• Guidance on how to signpost to additional services | **TRAINED IMPLEMENTERS**<br>• Increased knowledge of malnutrition causes/signs etc.<br>• Increased ability to identify older persons likely to be at risk<br>• Increased confidence to initiate conversations about malnutrition and provide advice / signposting | **TRAINED IMPLEMENTERS**<br>• Improved understanding of signs of malnutrition and action to take<br>• Initiate conversations about malnutrition and implement Checklist<br>• Deliver improved care regarding nutrition |
| **OLDER PEOPLE** | • Trained implementers<br>• Older people<br>• Place of initial conversation<br>• Copies of Checklist and associated materials | **Patient's Association Nutrition Checklist**<br>• Complete Section A (assess potential risk at an early stage)<br>• Complete Section B (and use the subsections)<br>• Signposting to support | **OLDER PEOPLE**<br>• Increased awareness of risk factors and signs of malnutrition<br>• Empowered to seek ongoing advice and access services<br>• Improved knowledge to meet dietary needs<br>• Improved food intake, appetite, weight gain, fluid intake | **OLDER PEOPLE**<br>• Increases in identification of risk of malnutrition<br>• Increases in receipt of appropriate information, nutrition advice and support<br>• Reductions in malnutrition<br>• Improved hydration |