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Development of a Core Outcome Set for Dysphagia Interventions in Parkinson's disease (COS-DIP): study protocol

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ABSTRACT

Introduction Current clinical trials on swallowing disorders (dysphagia) in Parkinson's disease (PD) apply a high variety of outcomes and different outcome measures making comparative effectiveness research challenging. Furthermore, views of patients and dysphagia clinicians when selecting trial outcomes have not been considered in the past, thus study results may have little importance to them. This study aims to develop an agreed standardised Core Outcome Set for Dysphagia Interventions in Parkinson's disease (COS-DIP), systematically measured and reported as a minimum for all clinical trials. It will also comprise guidance on outcome definitions, outcome measures and time points of measurement.

Methods and analysis The COS-DIP development will comprise five stages following established methodology: (1) a recent scoping review on all applied outcomes, their definitions, methods and time points of measurement in clinical trials in dysphagia in PD, (2) online surveys and focus groups with clinicians, patients, caregivers and family members to identify outcomes that are important to them, (3) an identified list of outcomes based on results of stage 1 and 2, (4) three round online Delphi survey with up to 200 key stakeholders to determine core outcomes and (5) two online consensus meetings with up to 40 representative key stakeholders to agree on all outcomes, definitions, methods and time points of measurement in the final COS-DIP.

Ethics and dissemination Full ethical approval was obtained from the Research Ethics Committee, School of Linguistic, Speech and Communication Sciences, Trinity College Dublin, on 15 May 2023 (HT27). Dissemination of the COS-DIP will be enhanced through presentations at (inter-) national conferences and through peer-reviewed, open access publications of related manuscripts. Lay and professional information sheets and infographics will be circulated through relevant patient and professional organisations and networks.

Trial registration number The COS-DIP study was registered prospectively with the Core Outcome Measures in Effectiveness Trials (COMET) database on 24 September 2021 (www.comet-initiative.org/Studies/Details/1942).

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A multidisciplinary study steering committee comprising experts from the field of speech and language therapy, core outcome set methodology, neurology, clinical trials in dysphagia in Parkinson's disease (PD) and a public research partner with PD is established to lead and conduct this Core Outcome Set for Dysphagia Interventions in Parkinson's disease (COS-DIP) study.
⇒ The COS-DIP will be developed following established core outcome set methodology with a mixed methods approach.
⇒ All key stakeholders including dysphagia clinicians, researchers and patients with dysphagia and PD, their caregivers and family members will be involved in the COS-DIP development.
⇒ One potential limitation at present is that participants must be proficient in English to participate in the study.

INTRODUCTION

The worldwide prevalence of Parkinson's disease (PD) has doubled in the last 25 years, and it is estimated that 8.5 million people were living with PD in 2019.[1] Throughout the course of the disease up to 80% of people with PD experience swallowing disorders (oropharyngeal dysphagia, OD).[2 3] This increases the risk of aspiration and hence developing pneumonia, which is a leading cause of death in people with PD.[4–6]

In OD interventions the aim is to make the intake of food and fluids as safe, sufficient and efficient as possible while maximising quality of life for patients and their families.[4] The clinical decision for the safest and most effective OD intervention in PD is based on available evidence. However, the transfer of clinical trial outcomes into clinical benefits for patients is oftentimes challenging. This may be due to missing relevant outcomes to patients and decision-makers, insufficient or no definition of outcomes, missing data, publication or reporting bias, lack of reporting of adverse events and missing data on the long-term effectiveness of the intervention.[7]

In a recent scoping review on swallowing outcomes in OD interventions in PD we

identified a high variability of outcomes applied in clinical trials. Furthermore, their definitions, outcome measurement instruments (OMI) and time points of measurement varied across included studies. Additionally, lack of information on outcomes, omitted outcomes and no inclusion of possible additional relevant outcomes were found to decrease the quality of clinical trials on OD in PD.[8]

Due to the heterogeneity of outcomes used in clinical trials in OD in PD, combining trial results (systematic reviews and meta-analyses) to direct treatment for people with OD in PD is challenging. Additionally, clinicians, patients, carers and families should be involved and asked what outcomes matter most to them in OD trials.

A solution to these challenges is the development and use of an agreed, standardised Core Outcome Set for Dysphagia Interventions in Parkinson's disease (COS-DIP) devised by key stakeholders including clinicians, researchers and patients.[9] This will enhance comparative effectiveness research for clinical trials on OD in PD.[7]

Aims and objectives

The aim of this study is to devise an agreed standardised core outcome set (COS) measured and reported as a minimum for all clinical trials for OD in PD. As a first step we established a preliminary list of outcomes based on identified outcomes in the literature in a recent scoping review.[8]

The objectives of this study are:

1. To further establish the list of outcomes by identifying OD in PD intervention outcomes that are important to clinicians, patients, carers and family members in online surveys and focus groups.
2. To determine core outcomes for the COS-DIP through a three round online Delphi survey with international key stakeholders.
3. To achieve consensus on the core outcomes included in the COS-DIP, their definitions, OMIs and time points of measurement through two online consensus meetings with representative international key stakeholders.

The online surveys and focus groups were conducted from January to October 2023. The online Delphi surveys are scheduled to start in mid-January 2024 and to be completed by April 2024. The online consensus meetings are scheduled to take place in May 2024.

Scope of the core outcome set

The COS-DIP will be devised primarily for clinical trials. It will cover all types and severities of OD in all individuals with idiopathic PD and all clinical interventions used to improve swallowing and reduce the risk of swallowing-related side effects (malnutrition, pneumonia, choking, etc). This COS will represent the minimum number of outcomes that trialists should collect, but it does not preclude them from collecting additional outcomes at their own discretion.

Identifying existing knowledge

A search of the Core Outcome Measures in Effectiveness Trials (COMET) initiative database (www.comet-initiative.org) was conducted prior to the beginning of this project (03 February 2021, last updated 05 June 2023) and revealed no planned, ongoing or published COS for clinical interventions for OD in PD.

Two published COS studies on PD in general, but not on OD specifically, were identified.[10 11] Both studies comprise outcomes related to swallowing but are not specific to dysphagia and both lack the involvement of all key stakeholders. However, the two studies provide preliminary evidence that OD in PD is relevant but a specific COS for OD in PD with involvement of all key stakeholders is needed.

METHODS

This study is developed in line with guidance from the COMET Handbook,[9] the Core Outcome Set-STandards for Development (COS-STAD) recommendations[12] and the guideline on how to select OMI for outcomes included in a COS by the COnsensus-based Standards for the selection of health Measurement INstruments and COMET initiative.[13] The study protocol is written in accordance with the Core Outcome Set-STAndardised Protocol statement.[14]

Study oversight

A Study Steering Committee (SSC) was established that will lead and conduct the development of the COS-DIP. The SSC is a multidisciplinary, international group and comprises experts from the field of speech and language therapy (SLT), COS methodology, neurology, clinical trials in OD in PD and a public research partner with PD. The SSC will be responsible for planning, advising and implementing each stage of the process: the study goals and timeline, study protocol, access to participants for the study, designing focus group interviews and surveys, analysing results, reporting findings, writing and publishing manuscripts and finally, disseminating the COS-DIP.

Patient and public involvement

As part of the SSC, a public research partner with PD is included in all stages of this research project.

Stakeholder involvement

Throughout this study three key stakeholder groups will be included. The definition of each group and planned ways of recruitment are outlined in table 1. Every attempt will be made to recruit a diverse range of participants to ensure that outcomes generated represent a wide range of perspectives.

The development of the COS-DIP comprises five stages. These are displayed in figure 1 and explained in detail in the following.

Table 1 Stakeholder group, definition and planned recruitment for the development of the Core Outcome Set for Dysphagia Interventions in Parkinson's disease

Stakeholder	Definition	Planned recruitment
People living with OD in PD, carers and family members	People diagnosed with OD in PD, people with experience of providing care for a family member and/or living with a family member with OD in PD.	Through national and international public research partners, relevant organisations, societies and patient support groups.
Healthcare professionals	People with ≥3 years of experience of providing care in a health setting for people with OD in PD, for example, SLTs.	Through national and international multidisciplinary professional dysphagia associations/networks, trial registries and central PD websites. Authors of included studies in the scoping review will be invited directly.
Researchers	People with ≥3 years of experience of undertaking research in the field of OD in PD.	

OD, oropharyngeal dysphagia; PD, Parkinson's disease; SLT, speech and language therapist

Stage 1: scoping review

In a scoping review, we identified all swallowing outcomes, their definitions, OMIs and time points of measurement applied in clinical trials in OD in PD.[8] The outcomes were mapped to the taxonomy by Dodd *et al*[15] and merged into a long list of outcomes version 1.

Stage 2: online surveys and focus groups

This stage will be a sequential explanatory mixed methods design comprising an online survey with dysphagia clinicians and an online survey with people with OD in PD, carers and family members. To understand the perspectives of people with OD in PD, carers and family members in more detail, focus groups will be conducted after the online survey.

Both the perspectives of people with OD in PD, their carers and family members as well as of clinicians are important. Researchers need to be able to trust that all stakeholders' views have been heard and included in the Delphi and later in the final COS-DIP.[9 16] However, these views were not represented in any included study in the scoping review, or it remains unclear.[8] As they might be different to those of researchers, it is beneficial to expand the long list of outcomes version 1 with outcomes that are particularly important to clinicians, people with OD in PD, carers and family members. Furthermore, this provides the opportunity to amend wording of outcomes for the Delphi survey by using patient and carer language and hence, make the Delphi survey more accessible to all stakeholder groups.[16]

Therefore, an international online survey was designed based on the list of outcomes version 1 to understand the perspectives of people living with OD in PD, carers and family members on relevant outcomes that should be measured in clinical trials in OD in PD. The survey was conducted online via Qualtrics (www.qualtrics.com). The terms used in this survey were developed together with the public research partner with PD from the SSC and approved by all SSC members. The survey was piloted by lay people and SLT students and was estimated to take less than 10 min to complete. Data will be analysed in R descriptively (rating of importance of outcomes in %) and

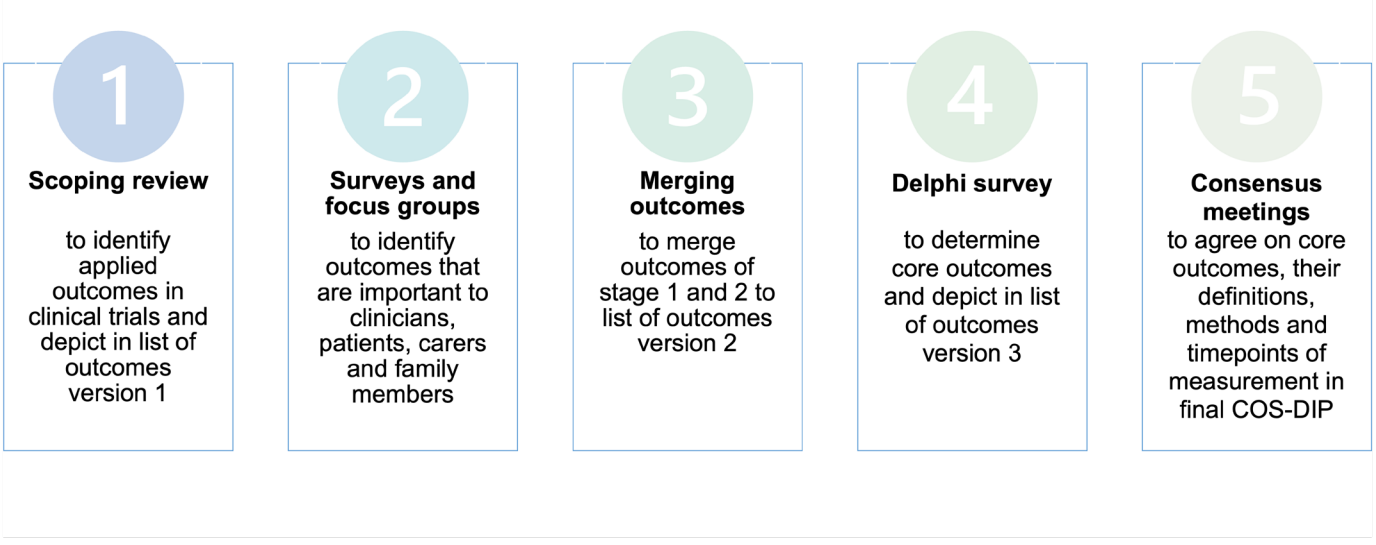

Figure 1 Stages during the development of the COS-DIP. COS-DIP, Core Outcome Set for Dysphagia Interventions in Parkinson's disease.

inferentially using Pearson's χ^2 test to determine if the rating of importance (important/not important) of each outcome is significantly different between the two groups (people with OD in PD and carers/family members).[17]

The results of the survey with people living with OD in PD, carers and family members will then inform the following online survey with clinicians. The procedure, questions and items will be identical except for the wording. The items will be phrased using terms that are commonly used in clinical practice instead of lay terms (eg, 'Changes in frequency of penetration/aspiration' instead of 'Changes in frequency of food or liquids going the wrong way – into the airway/windpipe'). The survey will be translated into different languages (Chinese, Italian, Spanish and German). This will allow us to send the survey to a wider community and to obtain a comprehensive understanding of the clinicians' perspectives globally while also following the COS-STAD recommendations.[12] These languages were chosen because of the well-developed services for people with dysphagia in the countries where these languages are spoken. The resources available to the research team were also a factor in choosing these languages. Translators will be encouraged to cross-check their translations with another colleague who is proficient in both English and their relevant language. The survey will be piloted on two clinicians and is estimated to take less than 15 min to complete. Data will be analysed in R using the same tests as in the previous survey.

Concurrently to the online survey with clinicians, focus groups with participants from the previous online survey with people with OD in PD, carers and family members will be conducted. The aim is to validate the findings of the previous survey and to clarify uncertainties that might have emerged from the survey and ultimately gain a deeper understanding of the participants' perspectives.[18] Approximately 30 participants will be involved in four focus groups with 7–8 participants each.[18] At the end of the online survey, participants will be asked if they would like to take part in subsequent focus groups. Those who signal interest, will be contacted via email. Each focus group will last approximately 60 min to keep the time demand on participants as low as possible. A semi-structured interview guide will be designed in accordance with recommendations by Keeley *et al*[16] and based on the survey results and in discussion with the SSC. All focus groups will be conducted virtually using Zoom platform to increase accessibility for participants. The interviews will be conducted by JH and MW and will be audio recorded, transcribed verbatim, pseudonymised and entered into NVivo V.12 Plus (QSR International, USA). Data will be analysed following Reflexive Thematic Analysis by JH.[19]

Four focus groups are planned in total as research has shown that more than 90% of codes have emerged after four focus groups and code saturation was reached at this stage.[20] Code saturation is defined by Hennink *et al* 'as the point when no additional issues are identified in data and the codebook has stabilized'.[20] Based on this, each consecutive focus group transcript will be analysed, and the number of new codes will be counted. If one or no new codes emerge, code saturation is reached.[21] If more than one code still emerges through the fourth focus group, further focus groups will be conducted until code saturation is reached.

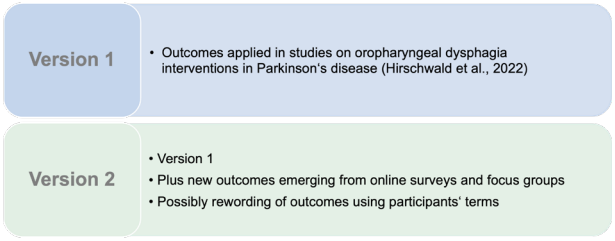

Figure 2 Development of long list of outcomes version 1 and 2.

In comparison meaning saturation is defined 'as the point at which we fully understand the issues identified and when no further insights or nuances are found'.[20] As we will not stratify focus groups by any participant characteristics, meaning saturation is estimated to be reached within the four focus groups as well. Meaning saturation will be assessed by reviewing each transcript successively and analysing whether new aspects, dimensions or nuances for each code emerge. As with code saturation, if no new meaning is identified for each code, meaning saturation is achieved.[21]

Stage 3: merging outcomes

The list of outcomes version 1 will be supplemented with outcomes that emerged in stage 2 through the surveys and focus groups. If considered appropriate, outcomes may be reworded with lay terms used by participants in stage 2 to increase the comprehensibility for all stakeholders.[9] Following discussion and agreement within the SSC, outcomes will be combined or dropped if they are considered to be overlapping in content or repetitious, subdomains may be added for better categorisation of outcomes and will be merged into an adapted list of outcomes version 2. See figure 2 for an overview of the development of the long list of outcomes version 1 and 2.

Stage 4: Delphi survey

A three round online Delphi (eDelphi) survey will be conducted to obtain participants' views on the importance of each outcome of the list of outcomes version 2. The Delphi technique will be applied as this allows us to collect responses anonymously and objectively, to prevent the impact of dominant participants and to include a large number of international stakeholders from a wide geographical range.[9]

Participants in this stage will be from all stakeholder groups listed in table 1. Using as large a panel as is practical, it is anticipated that at least 150–200 participants will be recruited for valid consensus with a comprehensive range of perspectives achieved.

All three round eDelphi surveys will be conducted through the online DelphiManager platform (www.comet-initiative.org/delphimanager). When designing

the survey lay terms will be used where possible to improve comprehensibility for all included stakeholder groups. The survey will be piloted to ensure face validity.[9] This will also inform the time needed to complete each eDelphi round.

In each round participants will be asked to rate every outcome according to their perceived importance on a 9-point scale as recommended by the Grading of Recommendations Assessment, Development and Evaluation Working Group.[22] The scales 1–3 represent limited importance, 4–6 importance but not critical and 7–9 critical importance. A button 'unable to score' and a text field for additional comments will be available.[9 23] A definition will be provided for each outcome. Each survey round will be open for 3weeks with an email informing the participants about the survey opening. Reminder emails will be sent to all participants who have not completed the survey after 2weeks.

Participants who agree to take part in the eDelphi will be assigned a code and therefore data will be pseudonymised. At the beginning of **round 1** participants will be asked to provide some general personal data (gender, age, nationality, stakeholder group, for patients: number of years since diagnosis). Participants will then be informed about the survey procedure. Participants will then be asked to rate the importance of each outcome. At the end of round 1, participants will be asked whether any important outcomes were missing and if so, to specify them in a provided comment box. This ensures that no key outcome important to each stakeholder group is omitted.[9 23]

In **round 2** the remaining outcomes and new outcomes identified from round 1 will be included. Participants will be shown their own score from round 1 with feedback on the percentage of scores of each outcome for each stakeholder group. They will then be asked to rescore the outcome, taking the feedback from round 1 into consideration.[9]

Likewise, **round 3** will include remaining outcomes and new outcomes identified from round 2. Participants will again be asked to rescore the outcomes based on the feedback from round 2.[9] At the end of round 3, participants will be asked if they are willing to participate in a consensus meeting in the next step. See figure 3 for an overview of the process of the three round eDelphi survey.

Adding/retaining/dropping outcomes

New outcomes will be added to the list of outcomes if they are suggested by at least two participants. Outcomes will be retained after each round if they meet the according 'consensus in' or 'no consensus' criteria as defined in table 2. All outcomes that will reach 'consensus out' will be dropped. Agreed outcomes and outcomes without consensus will form the list of outcomes for the following round.[9 24]

This approach will ensure that the burden on participants is kept to a minimum due to shortening the list of outcomes from one round to another. At the same time, starting with less rigorous criteria in round 1 will prevent outcomes dropping too early and will give participants the opportunity to rescore an outcome based on the feedback provided from the stakeholder groups.[9]

Missing data

To facilitate retention of participants in general only participants who replied to a pre-Delphi invitation will take part in the first round, contact details of the lead

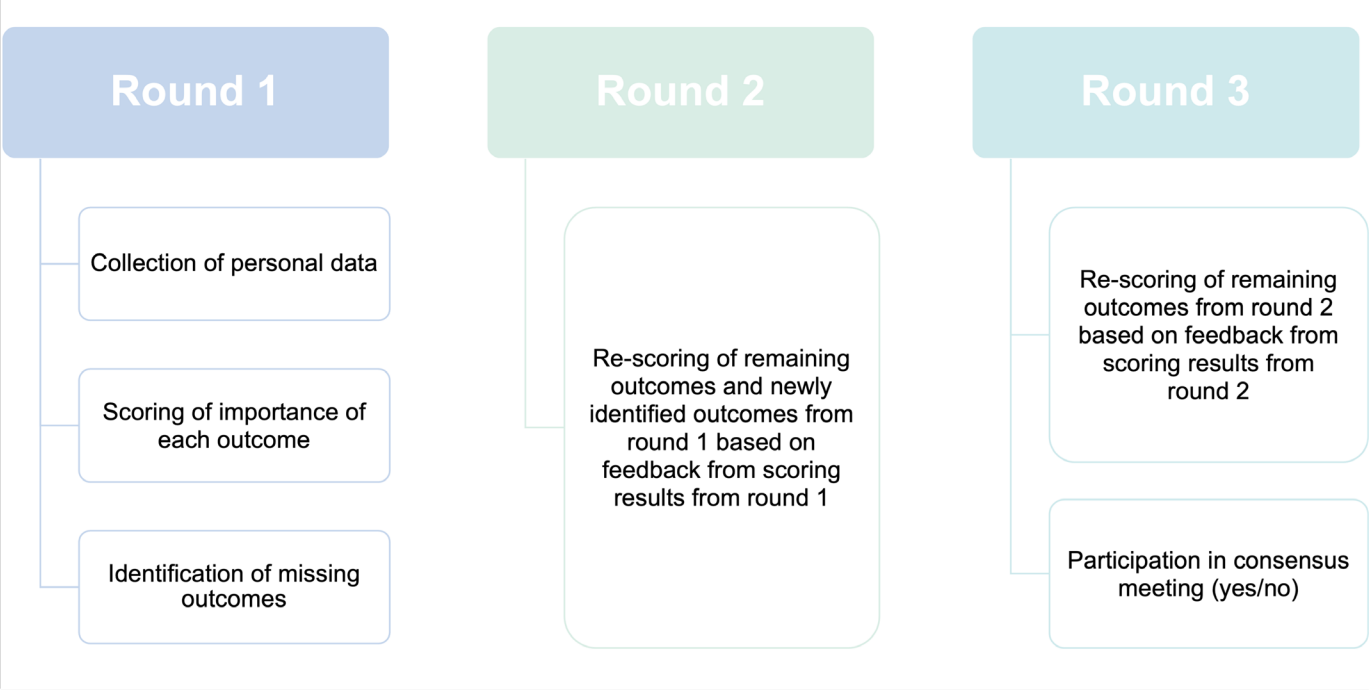

Figure 3 Steps for each round of the online Delphi survey.

Table 2 Definition of consensus in accordance with Blazeby *et al*[24] and Harman *et al*[27]

Consensus classification	Description	Definition	
		Round 1	Round 2+3
Consensus in	Outcome should be included in COS	≥50% scored 7–9	≥70% scored 7–9
Consensus out	Outcome should not be included in COS	<50% scored 7–9	
No consensus	Uncertainty about outcome importance		≥50% and <70% scored 7–9

COS, core outcome set.

researcher (JH) will be provided, participants are offered to be acknowledged in the published manuscript and the eDelphi will be concise, user friendly and not overly time-consuming to complete.[9 23]

A common challenge in Delphi surveys is that participants with minority opinions might drop out of the study, which can lead to overestimation of the level of consensus. In case attrition is higher than 20% personalised reminder emails about survey completion and current response rates will be sent. Only participants who completed the survey will be invited to take part in the following rounds to minimise attrition bias.[9 23]

From this stage, the list of outcomes version 3 will result and will be extended with definitions that achieved agreement and suggested definitions for those that did not achieve consensus.

Stage 5: consensus meetings

Two consensus meetings will be held virtually to facilitate attendance of participants from different time zones.[25] The aims are to discuss the results of the eDelphi survey, outcomes that have reached no consensus and to ultimately verify the core outcomes to devise a final list of outcomes including definitions of outcomes, OMIs and time points of measurement of outcomes for the COS-DIP.

Attendees at this meeting will comprise a 20% selection of all eDelphi participants. Only those who indicated to be willing to participate at the end of stage 4, will be randomly and equally selected from each stakeholder group. Prior to the meeting participants will be sent a reminder email with their individual eDelphi scoring from round 3. The meeting will be led by a moderator with experience in conducting consensus meetings.

Agreeing on outcomes included in the COS-DIP

The moderator will inform the participants about the results of the eDelphi and will elicit feedback on the preliminary COS-DIP and on outcomes with no consensus. Final voting on including or excluding outcomes (yes/no) will be carried out by using an electronic voting system. Outcomes that are voted ≥70% 'yes' will be included in the final COS-DIP.

Agreeing on definitions, OMIs and time points of measurement of outcomes

The list of outcomes version 3 with definitions used in the eDelphi will be extended by the OMIs and time points of measurement from the scoping review[8] in stage 1 before the consensus meeting. The moderator will inform the participants and elicit feedback about the definitions of outcomes, OMIs and time points of measurement. Final voting on agreement (yes/no) will be carried out by using the same voting system and criterion (≥70%) as for the agreement on outcomes. In the end, an agreed set of core outcomes, definitions, OMIs and time points of measurement for the COS-DIP will be generated.

DISSEMINATION

Promoting the COS-DIP and recommended measurements will be critical to adoption in clinical OD trials in PD. The awareness of the COS-DIP project will be enhanced through submissions for scientific presentations at national and international multidisciplinary conferences and through peer-reviewed, open access publications of related manuscripts, for example, the scoping review,[8] this study protocol, results of the online surveys and focus groups and ultimately the complete COS-DIP. Lay and professional information sheets and infographics will be circulated through relevant patient and professional organisations and networks.

Furthermore, a social media Twitter account (Research in Dysphagia and Parkinsonian Syndromes, @DysphagiaPhDs) was established through which the COS-DIP will be further disseminated. Additionally, a page on the Swallowing and Voice Centre website of Trinity College Dublin (TCD) was created to inform about the COS-DIP project in general and provide specific information for each stage of the project (www.tcd.ie/slscs/clinical-speechlanguage/dysphagia/COS-DIP-Research). Animated explainer videos were created using the online platform Vyond (www.vyond.com) to provide easy to understand and accessible information on the project. This will especially be helpful for lay people, such as people living with PD and OD and their family members. These videos are linked into the above-mentioned TCD website and will also be linked into emails to gatekeepers and potential participants and shared on Twitter to raise awareness of and to inform about the COS-DIP research project.

DISCUSSION

So far, there is no published COS for OD interventions in PD. The development of the COS-DIP will improve the interpretation and comparison of future studies and therefore enhance comparative effectiveness research to direct treatment for people with OD in PD. The COS-DIP study will involve three international stakeholder groups

to ensure that it is suitable and well accepted in future research.

However, as outlined by Williamson and colleagues[9 26] it will be important to regularly (re-) evaluate the COS-DIP as a means of validation in the future. This will ensure that outcomes are still relevant and important to all key stakeholders. It will also provide the opportunity to add or remove outcomes and to add or change new, validated OMIs, where applicable. Finally, it will be important to assess if and how the COS-DIP is successfully measured and reported in clinical trials on OD in PD.

Study status

This is version 1 of the COS-DIP study protocol, last edited on 20 December 2023. The COS-DIP study is ongoing, with a scoping review of the quantitative literature complete. The last stage of the COS-DIP research project is expected to be completed by June 2024. The SSC appreciates requests from those interested in participating in the COS-DIP study.

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Competing interests None declared.

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