

BMJ Open Talking scrubs: improving the health outcomes of patients with communication disability – a mixed method investigation of feasibility, effectiveness and clinician–patient concordance

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ABSTRACT

Introduction People without access to recognised and understood speech and/or written communication methods can experience exceptional disadvantage in health settings. This can result in poor health outcomes, lengthier hospital admissions and adverse events, including preventable deaths. Despite numerous attempts to integrate augmentative and alternative communication into health settings, the first-person ‘voice’ of the patient is often not accessible or prioritised, deferring instead to others, such as parents or carers, or the ‘best guess’ by healthcare professionals. The *Talking Scrubs* project aims to form a bridge to augmentative and alternative communication by locating key communication icons on scrubs (and scrubs/vest) to be used with patients (in and of themselves) and/or to prompt the use of patient individualised communication methods. The paper describes the methodological process for Stage 4 of the project. Prior stages involved investigating the concept, developing and validating instrument measures and co-designing and feasibility pilot testing the scrubs/vests. Stage 4 (this protocol) aligns with the diagnostic process, to test the feasibility and effectiveness of the scrubs intervention at two large, metropolitan medical centres with 5–10 general practitioners, approximately 30 patients and up to 10 flow-on diagnostic screening clinicians such as nurses and phlebotomists. Stage 4 is the first time the instrument measures will be applied and re-tested post-validation.

Methods and analysis Using mixed methods, Stage 4 will apply the communication self-efficacy instruments co-designed in Stage 2 and validated in Stage 3 to measure effectiveness of the scrubs intervention by comparing pre-intervention and post-intervention changes in both clinician and patient population groups. Qualitative interviews, agency recorded data and participant journal recordings (optional) will be used to identify feasibility. SPSS V.29 (IBM, Chicago,

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The mixed methods applied in this study are specifically designed to effectively encapsulate, collect and triangulate clinical discourse data between patients and clinicians.
- ⇒ The study applies multiple forms of mixed method result testing (triangulation) to an extent that it will be difficult for negative results, data errors and inconsistencies not to be blatant and easily identifiable.
- ⇒ The decision to hybrid partner clinician and patient participants within a clinical trial not only offers enormous scope for investigating a complex clinical problem but provides an additional layer of data triangulation and maximises the translation and application of results in real life settings.
- ⇒ The study is limited in sample size and does not accommodate a randomised controlled trial.
- ⇒ While we recognise its applicability and relevance across multiple medical areas, the study is limited to the diagnostic process.

Illinois, USA) will be applied to analyse participant communication self-efficacy measures and NVIVO V.10 (Lumivero, Denver, Colorado, USA) to the retrieved qualitative data.

Ethics and dissemination Stages 3 and 4 have ethics approval from the University of South Australia Ethics Committee identification number 206 930 and are registered as a clinical trial with Australia and New Zealand Clinical Research Trials (ANZCRT) with registration number 12625000490471p. Stage 1 (national survey) and Stage 2 (stakeholder focus groups) received ethics approval from Flinders University. Findings will be disseminated through national and international health translation platforms, publications, media and on the Talking Scrubs website.

Trial registration number ANZCRT with the registration number ACTRN12625000490471p.

BACKGROUND

Communication disability

Disability is commonly viewed from the perspective of the *medical model*, being a problem that exists in the body of an individual and requires medical treatment.¹ The social model of disability, by contrast, recognises and positions disability as resulting from disabling conditions external to the individual (such as the absence of inclusive adaptations).^{2,3} The social model provides a helpful framework for the study hypothesis: *when the patient's communication agency is understood and used (reflected back) by clinicians; when s/he has the first-person voice in their own healthcare; when s/he is no longer 'spoken for' but instead personally indicates their health concerns, feelings and consent, then the above-described problem(s) are likely to diminish or resolve.* Consistent with this model, the phrase *communication disability* (rather than terms such as *communication disorder*) is used throughout the study to reposition the problem and to include the vital role of the communication partner. It also acknowledges the interactive, two-way process of both understanding and being understood.⁴

Communication disability is associated with a range of conditions, including congenital, developmental and acquired health conditions such as cerebral palsy, autism, cleft palate, intellectual disability, multiple sclerosis, acquired brain injury, stroke, dementia and Parkinson's disease.⁵ It has also been noted in individuals with schizophrenia^{6,7} and other mental health conditions such as selective (situational) mutism.⁸ Communication disability can feature in many population groups; the increased prevalence with ageing and, in the short term, experienced by patients during intubation or other medical procedures.⁹ In 2015, Australia's population of 24 million included 1.2 million people with ongoing communication disability.¹⁰ Contrasting with the rights of an interpreter to facilitate healthcare upheld by the Australian government for people of non-English speaking backgrounds, no similar standard or pathway exists for people with communication disability.¹¹

Communication self-efficacy is a person's belief in their ability to control their functioning or succeed in a particular situation¹² and is identified as a critical predictor of numerous health behaviours, including the patient's need to ask questions, raise concerns and make preferences.¹³ The concept of communication self-efficacy is usually only applied to patients; however, recent studies identify its relevance to clinicians. Communication self-efficacy beliefs support the relationship between doctor and patient and are among *the most robust* antecedents of behaviour.¹⁴ When individuals do not believe they have a chance of succeeding in a specific area, they are unlikely to engage; a situation potentiated by poor communication self-efficacy experienced by health professionals providing services for patients with communication

disability.^{15,16} In a study concerning patients with intellectual and/or cognitive disability, medical practitioners showed diverse and unstandardised communication approaches and frequently did not directly engage the patient due to their estimation of their patient's decision-making ability.¹⁷ Despite concerns over patient consent, most physicians prefer to communicate with their patients' caregivers.¹⁷ This is underscored in findings concerning general practitioners (GPs) where all doctors of the study deferred to patient 'carers' and although some patients acknowledged they needed assistance, most objected to the practice of the doctor speaking directly to their carer rather than to them.¹⁸

Communication disability and health

People with communication disability face serious challenges accessing and participating in healthcare.¹⁹ Highlighted are the diverse experiences of population groups, including children and adults with lifelong disability as well as patients with later onset disability or short-term loss of verbal communication such as intubation in emergency wards or intensive care units.²⁰ Medical encounters often involve high-stakes interactions where patients with communication disability and providers can live in 'parallel universes'.²¹ This disparity between patients with communication disability and clinicians is causally intertwined with social determinants of health, perceptions of disability (previously mentioned models of disability) and the existence of systemic ableism in health settings.²² Furthermore, the unique challenges confronting patients with communication disability are in addition to those routinely experienced by patients in healthcare settings such as a range of barriers to effective communication (eg, lack of medical knowledge and low trust in physicians).²³ The results of which are reflected in escalating evidence of preventable adverse events such as diagnostic and medication errors, unnecessary patient suffering, longer hospital stays and unnecessary healthcare expenditure.^{24–26}

Of particular concern is the connection between preventable fatalities and communication disability. A recent scoping review described causes and contributors of deaths among people with intellectual disability in Australia.²⁷ Findings identified that communication disability was present among most persons who had died. Poor access to communication, among other social determinants of health such as lower education levels and ableism, is found to contribute to the inequality of cancer outcomes for people with intellectual disability.²⁸

Higher rates of physical and chemical restraint are reported for patients who cannot communicate verbally.^{29,30} There is also growing evidence of barriers to accessible and timely diagnosis and screening of mental health conditions going undiagnosed and untreated, alongside major gaps in accessing therapeutic support for people with communication disability.^{31–33} Despite very limited data across health disciplines, a few studies centred on GPs provide some insights to the problem,

including the previously mentioned study in which all GPs studied were reliant on carers when undertaking consultations.¹⁸ In a more recent study, GPs expressed their concerns about their difficulty communicating with patients with intellectual disability, which reduced effective history-taking, impeded relaying and planning of medical conditions or procedures and undermined the ability of patients to make informed decisions and give informed consent.³⁴

Inherent in these communication-related shortfalls are also financial consequences. A US study identified and costed communication-disability specific events, asserting facilitation of patient-provider communication represents an ethical and financial imperative wherein an estimated annual cost of US\$6.8 billion could be saved by addressing communication barriers.³⁵ Furthermore, a swathe of uncoded implications is revealed in the elevated preventable hospitalisations of people with communication disability.³⁶ Contributing factors include poor uptake and engagement with preventive healthcare by GPs who lack confidence in providing healthcare for people with communication disability.^{16 18}

In recent years, interventions seeking to improve communication, environmental supports for communication and health service delivery have increased,³⁷ fostered by the message that clinicians must be prepared to accommodate diverse communication needs of their patients with disability.¹⁷ Yet, despite more health staff receiving training, and communication tools entering (but becoming lost in) health systems, there is insufficient momentum to support the growth of a culture which accepts and effectively integrates augmentative and alternative communication.³⁸ Meanwhile, reports of caregiver dissatisfaction and distress attributed to poor communication with clinicians continue to mount.³⁹

Why scrubs?

The overall aim of the *Talking Scrubs* project is to help resolve the communication barriers by co-designing a solution not only capable of offering a communication pathway but simultaneously affecting cultural-adaptive change in health settings. In recent years, the evolution of scrubs has been shaped by a desire for fashion responding to⁴⁰ and a growing trend of wearing scrubs outside clinical settings, such as in cafes and shopping spaces.⁴¹ Our project enters the evolution of scrubs not from a position of fashion or versatility but in the endeavour to improve communication in health settings. We perceive scrubs, like communication, to be embodied, personalised and kinetic. The targeted use of the clinical uniform provides an opportunity to help shape a workforce culture in welcoming the communication capacity of patients often considered 'unreachable'.

Study phases

Stage 1 . Survey (completed). This national stakeholder survey received 293 responses, with 71% indicating their early opinion of the idea of using icons on scrubs

as either 'great or good'. Out of the 293 respondents, 108 participants were clinicians with nurses (n=41) and doctors (n=27) forming the highest clinician participant population groups. Clinicians indicated an overall low confidence in communicating with patients who cannot speak. When asked, "From your perspective, how serious a problem is communicating with patients who cannot talk or talk clearly enough to be understood?" Out of the 108 clinicians, 61% (and almost all doctor participants) indicated on the highest scale that this is *a serious problem that poses a risk to the health and well-being of patients*. The survey captured participant views on essential vocabulary, the style of icons and positioning, as well as the colour of the scrubs. Participants were also asked to describe their thoughts, especially related to risks and concerns, and were also invited to express their interest in joining a focus group (Stage 2).

Stage 2. Focus groups (completed). Recruited 25 stakeholders (including three people with intellectual disability, parents, doctors, nurses, speech pathologists, intellectual disability advocates and health administrators) through online meeting over a 4-month period. Participants were separated into two mixed population groups to plan and co-design protocols for safe use, discussing concerns identified in Stage 1 such as issues of risk of touch and personal body space. The focus groups also explored scrub design templates (scrubs top and vest) and clinician training to begin early discussion on two survey instruments to measure the communication self-efficacy of clinicians (SE:CD17) and patients with communication disability (SE:CH17).

Stage 3. In progress Following a UniSA Slingshot Grant: validation testing of the SE:CD:17 and SE:CH:17 instruments and a small-scale pilot introduction of adapted scrubs to health setting(s). See [table 1](#) which reveals the first five questions of the SE:CD17 and SE:CH17 instruments.

Stage 4. Proposed to be scheduled from April 2026 to April 2028. **Stage 5.** On completion of Stage 4, formation of a social enterprise where Talking Scrubs is registered and co-led by people with disabilities.

Table 1 provides an example of SE:CH/ SE:CD instrument items co-designed in Stage 2, and constituting questions or themes from the communication self-efficacy measures developed by other researchers^{14 42} The SE:CD17 is Self-Efficacy with people with Communication Disability. It has 17 items (questions) and is used *by clinicians*. The SE:CH17 is the Self-Efficacy with Health Workers (clinicians) designed with and *used by people with communication disability*. The SE:CD17 is also available in Easy Read and augmentative and alternative communication (AAC) formats. The 17 items of both instruments are correlated and can be compared during analysis. **Table 1** provides an example of the first three of the 17-item survey instruments.

Table 1 Example of items included in the survey instruments

SE:CD17	SE:CH17
1. How confident are you that you can identify how the patient communicates?	1. How confident are you that you can tell (doctor X) how you communicate?
2. How confident are you that you can successfully identify how the patient conveys yes, no (and neither)?	2. How confident are you that you can show (nurse Y) what you need to communicate?
3. How confident are you to ask the patient yes, no questions?	3. How confident are you that you can show (doctor X) how you say yes and no?

Study design

Research questions

The Stage 4 investigation centres on four questions. (1) Are the scrubs and vest acceptable and achievable for use by GPs and on-site diagnostic screening clinicians? (*Feasibility*) (2) Does the use of the scrubs increase the perceived communication self-efficacy of patient and clinician participants? (*Effectiveness*) (3) Does the use of scrubs/vests intervention improve concordance in the diagnostic process? (*Feasibility and concordance*) (4) Are the instrument measures performing as expected?

The diagnostic process model forms the framework on which the study questions are investigated. Our model (figure 1) is adapted from the Institute of Medicine Committee on Diagnostic Error in Health Care model⁴³ but further incorporates and breaks down the components of communication-dependent functions: ‘engaging’, ‘identifying’, ‘describing’, ‘discussing’, ‘giving consent’ and ‘planning’, and includes the communicative exchange of diagnostic testing, medication patterns, population screening history as part of a diagnostic process. We posit

the diagnostic model follows a more circular than linear trajectory, which is reflected in our adjustments to the model. We align the primary functions of successful diagnosis with required communication functions (concordance) between the patients and GPs, and the flow-on diagnostic screening performed by on-site nurses and phlebotomists. Figure 1 helps illustrate how deeply implicated the diagnostic process is in the ‘taken for granted’ realm of communication. While it may seem like an obvious point to make, it forms the integral first step for clinicians conceptualising their vital role as communication partners.

METHODS

The study tests feasibility, effectiveness and applies (for the first time) the validated instrument measures. *Feasibility* is approached using pre and post semi-structured and open question clinician and patient participants’ interviews, as well as journal/scrap book recordings (where participants elect to do this). With the consent of participants, the use

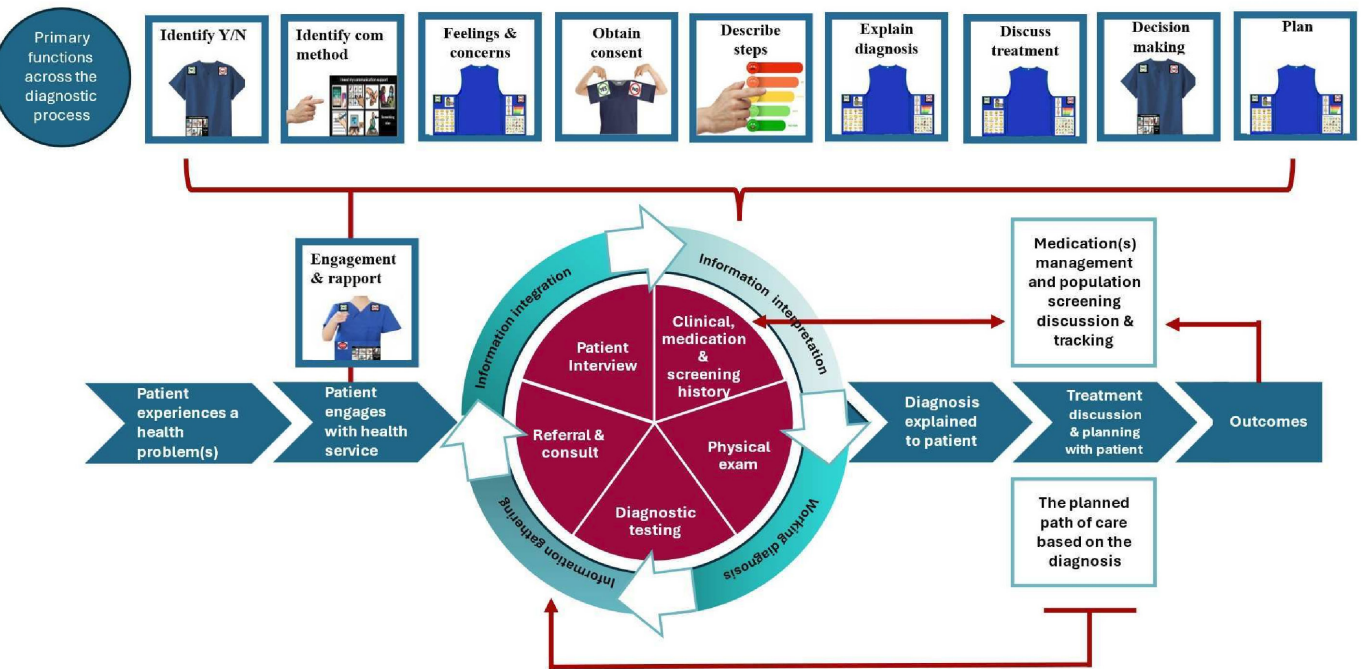


Figure 1 Adapted diagnostic process model framed on the Institute of Medicine Committee on Diagnostic Error in Health Care model.⁴³

of the scrubs/vests will be video recorded for the purpose of testing feasibility. Interview questions will explore ease of use, successful/unsuccessful sessions (how many and why), likeliness to adopt and participant recommendations. *Effectiveness* is measured by a comparison of pre-survey and post-survey scores triangulated with resultant descriptive interview themes.

To measure improvements in *concordance* rates between patient/clinician, we used the Capability, Opportunity and Motivation (COM)-B, a behaviour change model, by placing the scrubs intervention within the COM structure of the model.⁴⁴ Concordance is reflected in such things as the building of rapport between patients and clinicians; minimal patient involvement in treatment decisions being indicative of poor concordance.⁴⁵ The COM-B model guides clinician and patient participants to feel physically and psychologically able to perform a behaviour (C), have the social and physical opportunities to be able to implement the behaviour in the practice context (O), and have the desire/need to perform the behaviour (M-B). We use the pre-qualitative and post-qualitative interview to include COM-B specific questions. We compared these results with video recordings (where available) and agency records (where obtainable) such as attendance patterns, diagnostic screening history and existing patient evaluation processes. Statistical and descriptive data of health pattern changes drawn from site-based records will be gathered, for example, patient attending services and incident reports (including adverse events and code blacks) and qualitative recordings (journal/pictorial scrapbook) of clinician and patient thoughts and observations. Agency records will be collected pre-intervention and 6 months after the completion of the interviews to avoid the direct influence of the study on factors such as patient attendance and flow-on screening. Participants will also be asked to provide feedback on the survey instruments.

Data analysis

As illustrated in table 2, analysis is threaded from the research questions, collection method and data content. Statistical application (SPSS V.29, IBM, Chicago, Illinois, USA) is used to undertake analyses of the survey instrument responses comparing pre-survey and post-survey responses. The 17 items of the SE:CD17 and SE:CH17 surveys are designed for cross-population group comparison. A qualitative programme will be used to thematically analyse the content of the qualitative interview data. The quantitative and qualitative results are compared for data triangulation and thematic consistency. NVIVO V.10 (a qualitative application) is used for analysis of participant recorded journal/scrap book material (depending on the size and volume of responses).

The efficacy of the SE:CD17 and SE:CH17 instruments is analysed using content analysis, focussing on participant responses to semi-structured questions about using the tools. The instrument is triangulated for consistency with qualitative data collected during interviews.

Patient and public involvement

From its earliest beginnings, the Talking Scrubs project has maintained close involvement with people with lived experience of communication disability, including two co-researchers with cerebral palsy. Stage 2 of the project involved a series of focus groups. The participants were split into two smaller balanced groups with equal number of people with communication disabilities, clinicians, augmentative and alternative communication (AAC) experts, family members, disability advocates and research team members. The focus groups not only were instrumental in the co-design of the scrubs intervention but assisted in the careful planning of protocols for safe and comfortable implementation in the testing stages.

Participants of this study are clinicians located at the two partner sites and their patients with communication

Table 2 Questions, data collection methods, data content and analyses

Questions	Collection method	Data content	Data analysis
Are the scrubs/vests acceptable for use by GPs and on-site follow-on diagnostic screening clinicians?	Qualitative interviews and video recordings and participant journal recordings	Themes arising from the experience of using scrubs/ vests (including during training)	Feasibility themes and content analysis using NVIVO-10; consistency/correlations with survey scores
Does the use of scrubs/vests increase communication self-efficacy of participants?	Baseline and post SE:CD17 SE:CH17 surveys and interview	Pre-survey and post-survey scores and qualitative themes	Statistical comparisons of baseline and post-survey scores using SPSS V.29; consistency with interview content
Does the use of scrubs/vests improve concordance of the diagnostic process?	Qualitative interview questions centred on COM-B model indicators, video recordings, and baseline and post-study agency records	Participant perceptions of changes in patient-clinician relationship (eg, attendance, successful flow-on screening, etc)	Comparison of COM-B themes drawn from baseline and post-study interviews and video recordings
Are the instrument measures effective and acceptable?	Qualitative interviews	Feasibility themes; measures are consistent with descriptive themes	SPSS V.29 results and NVIVO V.10 themes
COM, Capability, Opportunity and Motivation; GPs, general practitioners.			

disability who volunteer to participate in the study. We seek to recruit and train 5–10 GPs (primary clinician participants) and 5–10 next workflow clinician participants (nurses and phlebotomists) to assist in the testing of the scrubs. A large GP practice in Adelaide central business district (CBD) has confirmed GPs and registered nurses. We are seeking a sample of 30 patient participants with communication disability to help test the scrubs at the varying points across the GP-initiated diagnostic process.

Inclusion criteria

- ▶ GPs providing diagnosis services for patients with communication disability.
- ▶ Patients with communication disability with health concerns that require diagnosis.
- ▶ Flow-on, on-site, clinician colleagues of the GPs who will perform diagnostic screening services for the patient as requested by the GP and consented to by the patient.

Exclusion criteria

- ▶ There is no diagnostic requirement involved for the patient.
- ▶ Flow-on diagnostic screening clinicians who are external to the site agency.
- ▶ Patients without communication disabilities, such as those from non-English speaking backgrounds.

Recruitment of participants will happen from the testing sites; the study will be advertised via multiple formats, including a letter to eligible existing and ongoing patients informing them of the study and inviting their participation. Approved recruitment resources will be displayed in patient areas of testing sites (eg, waiting room poster). Other approved recruitment resources such as the participant information sheet (Easy Read) will be displayed in the waiting areas. Where feasible, study advertisements will be included in newsletters of testing sites.

When a potential participant is identified (either through a third party or self-referral), the partner agency will alert the research team. The chief and a second researcher will be located at the clinic sites and will ensure participation criteria are met and offer to explain to patients the study in further detail. To be eligible to participate in the study, patients must be adults with communication disability (where verbal communication is frequently not understood by others) as identified by the patient or their support system. A researcher will be on-site to assist with recruitment and to conduct a brief interview and survey with patients. The prospective patient participant will be invited to read or listen to the study information sheet in Easy Read and if they are interested in participating, sign (or mark) the consent form. The chief researcher has expertise in the processes for obtaining consent in population groups with communication disability (including intellectual disability). Participants are provided with a range of accessible options for responding to consent questions such as low and

high technology pictorial formats and the inclusion of a 'best advocate' if required to assist with the consent process, which is evidenced in the prior work of the chief researcher.^{46 47} Clinician participants are required to read the study information sheet and sign the consent form prior to participating in the study.

Evaluation is undertaken throughout the project. A dual password-protected evaluation structure will be established to measure our performance against milestones and anticipated outcomes. In addition to the set research questions, informal feedback will be gathered about how participants (and others such as family/carers, agency staff) experience the research process itself. We are keen to know what bystander stakeholders think of the scrubs, vests, training and the survey instruments. This information will be collected by the research team, using researcher journalling reported to the steering committee. Two video blogs will be produced to record the research process and describe the forming of research partnering with people with lived experience of communication disability. Partnering and sharing power improves relevance and usefulness of research outcomes.⁴⁸

The project procedure (intervention) will take the following steps on recruitment of participants:

1. Clinician participants will participate in the first interview (face-to-face or online) at a time that suits them and complete the SE:CD17 survey instrument (30–45 minutes duration).
2. The clinician participants attend a scheduled on-site induction training (2 hours) on use of the scrubs and vests, including watching a short video (developed in Stage 3). This video shows the practical steps of using the scrub top, referring to the co-designed protocols. The training will outline such things as identifying how someone indicates 'yes', 'no', 'unsure', the process of asking for consent and responding when consent is denied and working with accompanying support workers or family members to ensure the first-person 'voice' of the patient. Additional resources will be provided to clinicians in case they wish to further develop their knowledge. These resources include an overview of AAC as relevant to people with intellectual and communication disability. A basic introduction to observing, waiting and listening (OWL) technique⁴⁹ and to *Partner-Assisted Scanning* will be provided.⁵⁰
3. At the completion of the training, clinician participants will be invited to 'test' or check their correct use of the scrubs with members of the research team (including community co-researchers with intellectual and communication disability). This opportunity will also be made available at the respective clinical testing site as members of the research team will be located at and/or travel across the sites during the data collection stage of the project.
4. Once the clinician participant and chief researcher is confident about their use of the scrubs, the recruitment and testing with patients can proceed.

5. As earlier mentioned, patient participants (including established and new patients) are recruited from the respective clinical sites by the clinical site staff and researcher. The consent process, pre-interview and survey (SE:CH17) will be conducted at a time(s) suitable to the participant at the medical site or at other locations as negotiated with the participant and may be done online (via MS Teams or Zoom). It may also be possible to conduct the consent process and baseline interview/survey immediately prior to the appointment with the GP if the patient is willing and able to attend the scheduled appointment at least an hour prior. The consent process will include a question asking participants for consent to (their use of the scrubs) being video recorded. Video recording is not compulsory and therefore a decision to not provide consent for this will not exclude the participant from the study.
6. The chief investigator BJMDP will closely oversee the consent of patient participants and will assist fellow researchers to build their skills in navigating the consent and use of inclusive research methods with participants with complex disabilities.
7. Patient participants will be informed of the intention of their GP to use the scrubs and vest.
8. At the end of the consent process, clinicians (and patient participants likely to have ongoing appointments with the same GP over the 12-month active testing of the scrubs) will be invited to keep a journal or picture/scrap book to record their experience and observations engaging with the project.
9. If a diagnostic test is required and can be performed within the partner practice (eg, blood test, urinary tract infection screening and ECG) then this will be offered to the patient within the clinic or given the option of choosing an external clinic (as per usual practice).
10. In the case of completion of a diagnostic process, including once-only GP appointment (and/or screening where the intervention has been used) but with no further appointment(s) booked, patient participants will be asked to repeat the SE:CH17 in relation to the service they just received. This may occur immediately after the appointment or at a time that suits the patient.
11. For clinician participants, two interviews and survey responses (before and after the use of the scrubs) are all that is required. Clinicians can, if they wish, answer the SE:CD17 after each patient participant appointment as it may provide them (and the study) with a more incremental understanding of communication self-efficacy changes; however, it is not necessary (or feasible in settings/situations where there may be waiting patients).
12. As indicated in point 11, at the completion of the study, clinician participants will be asked to undertake a repeat of the SE:CD17 instrument and will be re-interviewed.

Outcome measures of the study are listed for each of the fields of investigation.

Feasibility

- Comparison of pre and post-interview core themes drawn from descriptive interview analysis as aligned with feasibility measures of acceptability, relevance and usefulness.
- Comparison of pre-interview and post-interview core themes with journal entry data.
- Consistency of themes against statistical survey instrument data.

Effectiveness

- Statistical changes shown in the pre-survey and post-survey results.
- Qualitative themes aligning with statistical changes.

Concordance

- COM-B measures evidenced in qualitative data.
- Consistency of COM-B measures with survey instrument data and other qualitative themes.

Confirmation of the effectiveness of the validated communication self-efficacy instrument measures.

The project structure

The timeline

Stage 4 is designed to operate over 2 years. The first 3 months will involve the establishment of the project with training of clinician participants; it is expected to commence around the fifth month and the first recruitment of patient participants will be at 6 months. The next 6–12 months will involve the active study period (clinicians and patients testing scrubs). The flexibility in the timespan for testing scrubs is to accommodate time to recruit enough patient participants. We have determined that it is also acceptable for clinician and patient participants to continue using the scrubs for the full 12 months if they wish.

The research team

Studies highlight the value and efficacy of research and resultant health outcomes for individuals when patient engagement is a key feature of study protocols. The research team consists of people with lived experience of communication disability, medical specialists and research clinicians, primary health and disability health researchers, speech pathologists and a biostatistician. The project is actively seeking funding to enable the paid recruitment of community co-researchers to assist the project in such areas as training and ongoing co-design.

Overseeing the project is a steering committee consisting of health and medical researchers, agency partners, people with communication disabilities, family members, speech pathologists and other AAC experts. Some of the steering group members are drawn from the Stage 2 focus groups. As outlined in the 'patient engagement' literature, studies that involve persons interventions are designed for, in all decision-making processes, make resulting evidence more useful and improve health and healthcare outcomes for individuals.^{51 52} The steering

committee is fully established in the first month of the first quantile (3 months). The steering group will meet prior to the commencement of the study to assist in the detailed preparation of the study, raise questions, clarify steps and (where possible) plan for unexpected events. This is a crucial stage of ensuring the details of conducting the research, including participant training needs, interagency referrals and methods delivery are co-designed to be disability encompassing (accessible and respectful). It is important that the steering committee is comfortably adapted to group member needs for accessible and shared input and flexibility around the practices and cultures of partnered services. Regular steering committee meetings will coincide with the review of milestones and written evaluation reports.

Ethics and dissemination

All participants of this study will provide their informed consent and will be aware of their right to withdraw from the study at any point. Concerns about privacy mean that participants in this study may choose not to video record their use of scrubs; herein, our data will be limited to instrument recordings, interviews and journal notes. If the scrubs prove to be valuable to participants (ie, those with the most to lose if their scrubs are withdrawn), detachable icons and communication boards will be provided to health professional participants to use post study. Participants of the study will be invited to receive study results either directly sent in an email or through the participating health settings.

Thus far into the project, we anticipate a much wider group of stakeholders than GPs and flow-on diagnostic clinicians as having potential interest in the results of this study. As mentioned earlier, there are other population groups and health professionals that might attribute benefit from either the scrubs/vests intervention or the communication self-efficacy instruments or both. These groups may include (and are not limited to) intubated patients, clinicians undertaking mental health assessments, paediatricians and pre-linguistic children, patients with age-related cognitive decline or dementia, and even patients who may, for whatever reason, find it difficult to or are unable to talk. Findings will also be presented at relevant conferences and provided to disability and health agencies to publish on their websites and social media pages.

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Contributors BJMDP first author and guarantor—conceptualisation, literature review, design, methodology and full first draft. AKF—major edits and methodology. JK—edits and Aboriginal cultural input. MP—conceptualisation and lived experience translation. MW—edits and intellectual disability translation. AE—quantitative methodology input. CE—minor edits. JT—minor edits. EW—minor edits.

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Competing interests None.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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