Including migrant oncology patients in research: A multisite pilot randomised controlled trial testing consultation audio-recordings and question prompt lists

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ABSTRACT

Background: Oncology patients who are migrants or refugees face worse outcomes due to language and communication barriers impacting care. Interventions such as consultation audio-recordings and question prompt lists may prove beneficial in mediating communication challenges. However, designing robust research inclusive of patients who do not speak English is challenging. This study therefore aimed to: a) pilot test and assess the appropriateness of the proposed research design and methods for engaging migrant populations, and b) determine whether a multi-site RCT efficacy assessment of the communication intervention utilising these methods is feasible.

Methods: This study is a mixed-methods parallel-group, randomised controlled feasibility pilot trial. Feasibility outcomes comprised assessment of: i) screening and recruitment processes, ii) design and procedures, and iii) research time and costing. The communication intervention comprised audio-recordings of a key medical consultation with an interpreter, and question prompt lists and cancer information translated into Arabic, Greek, Traditional, and Simplified Chinese.

Results: Assessment of feasibility parameters revealed that despite barriers, methods utilised in this study supported the inclusion of migrant oncology patients in research. A future multi-site RCT efficacy assessment of the INFORM communication intervention using these methods is feasible if recommendations to strengthen screening and recruitment are adopted. Importantly, hiring of bilingual research assistants, and engagement with community and consumer advocates is essential. Early involvement of clinical and interpreting staff as key stakeholders is likewise recommended.

Conclusion: Results from this feasibility RCT help us better understand and overcome the challenges and misconceptions about including migrant patients in clinical research.

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1. Introduction

Globally, migrants and refugees face significant barriers in accessing safe and equitable healthcare [1,2]. Language limitations, unfamiliarity with host healthcare systems and other social and cultural challenges contribute to disparities in healthcare access, resulting in poorer outcomes, particularly for those diagnosed with non-communicable diseases such as cancer [2-4]. Communication barriers, such as limited English proficiency, impact on cancer knowledge, understanding of diagnosis and prognosis, and participation in health-related behaviours such as cancer screening and/or treatment decision-making [3,5,6]. Improving healthcare communication for migrant and refugee oncology patients is, therefore, important. Innovative interventions designed to improve communication, understanding, and participation such as question prompt lists (QPLs), which are standard lists of common questions asked by patients, and audio-recordings of consultations have been found to be efficacious in English-speaking oncology populations [7]. However, there is limited research regarding their effectiveness, acceptability, and feasibility in migrant populations [8,9].

Typically, there is low representation of migrant and refugee populations in clinical research due to perceived language, literacy, and communication difficulties, despite ready access to interpreter and translation services [10,11]. Exclusion is often deliberate, justified by assumed additional time, cost, and research design considerations [12]. However, inclusion of migrant populations in clinical research is necessary for generalisability outcomes, and for ethical and legal reasons [11,12]. To be successful and useful, research must employ culturally competent methods relevant to the specific needs of these groups [13]. Consequently, a better understanding of barriers and enablers to conducting research in migrant populations is needed. Feasibility studies which explore research methodologies for people who require interpreters can inform effective future research in migrant populations.

Given the language barriers faced by migrant populations when diagnosed with cancer, research which aims to develop and test in migrant populations, and to b) determine the feasibility of a multi-site RCT efficacy assessment of the INFORM communication intervention comprising consultation recordings and question prompt lists using these methods.

2. Material and methods

2.1. Study design

This study was a mixed-methods parallel-group, randomised controlled pilot feasibility trial. To achieve the study aims, the following pilot feasibility objectives [16] were employed:

1. Assessment of screening and recruitment processes: recruitment rates; inclusion criteria; and adherence and withdrawal rates for all participants.
2. Assessment of design and procedures: staff hiring and training; interpreter bookings and cancellations; clinician barriers, facilitators, and availability; appointment delays; intervention delivery; cultural considerations and patient feedback.
3. Assessment of time and costing: time spent by project team on recruitment, intervention delivery, questionnaire delivery, translation and transcription, patient contact, and data management.

Ethics approval was received at both participating outpatient oncology services in Melbourne, Australia. This study was registered prospectively with the Australia and New Zealand Clinical Trials Registry (Trial ID: ACTRN12616001538437).

2.1.1. Future full-trial endpoints

The primary endpoint selected for the full-scale trial is increased information recall. Research has demonstrated that patients immediately forget up to 80% of information provided in a medical consultation by a health professional [17]. Further, information that is retained is often remembered incorrectly [17] Provision of consultation recordings to facilitate patient ability to re-listen to key medical information was therefore hypothesised as an effective intervention to improve memory and recall. Methodology for quantifying information recall was developed as part of the RCT and is reported elsewhere [18]. Secondary endpoints include: transitory anxiety, unmet needs, and satisfaction with care and communication. The measures used to assess these endpoints are listed in the Data Collection section below. Note, however, responses to study measures were not used to estimate the population variance or potential efficacy because the sample size was too small to ensure precise estimation [19].

2.1.2. INFORM communication intervention

The communication intervention comprised: an oncology-specific QPL comprising 22 suggested questions for patients to ask their health professionals in the LOTE (Arabic, Greek, Mandarin or Cantonese); cancer information fact sheets in the LOTE; and an audio-recorded copy of the participant’s oncology consultation.

2.1.3. Consumer involvement

Arabic, Greek and Chinese consumer advocacy members of the project steering committee provided input into trial design and materials, research questions, and possible burdens arising from the intervention. This advice was integrated into the trial methodology [14].

3. Setting

Data were collected in two tertiary healthcare facilities with dedicated oncology services in Melbourne, Australia: at Peter MacCallum Cancer Centre for eight months (August 2015 to April 2016) and at Northern Health for 10 months (June 2015 and April 2016).

4. Participants

Migrant oncology patients were the primary participant group in this study; however, all individuals present in the audio-recorded consultation also provided informed consent including: health professionals, interpreters, and attending family/support people.

4.1. Migrant oncology patients

Patients aged 18 years of age or older; with a scheduled oncology consultation booked with an Arabic, Greek, Mandarin or Cantonese professional interpreter at one of the participating sites during the data collection period were invited to participate. Patients were excluded if
they were: in a therapeutic clinical trial; too unwell; hearing, vision, or speech impaired; self-identified as non-literate in their primary language; or diagnosed with a cognitive or psychological disorder.

4.2. Oncologists and interpreters

Prior to commencing patient recruitment, all oncologists treating patients diagnosed with Head and Neck, Lung, Urology and Gastrointestinal, Gynaecological, Haematological, and Bone and Soft Tissue cancers at both participating sites were invited to participate. Likewise, all interpreters certified by the National Accreditation Authority for Translators and Interpreters (NAATI) providing language services in Greek, Arabic, Mandarin and Cantonese at both sites were invited to participate.

4.3. Sample size

We intended to recruit a maximum of 80 participants (20 from each language group) during a 10 month period. The target sample was pragmatic, and aimed to assess appropriate recruitment targets and rates for a future full-scale RCT.

5. Procedures

5.1. Bilingual research assistants

Bilingual Research Assistant (RA) staff fluent in English and one or more of Arabic, Cantonese, Greek, or Mandarin were hired to recruit and coordinate patients’ participation. All RAs were trained to ensure that the trial adhered to Good Clinical Practice (GCP) and to establish formal qualitative interview skills. Monthly round-table meetings were conducted with all RAs to update on project progress, procedures and to identify and resolve any issues and challenges with trial operations. Potentially eligible patients were identified by screening interpreter booking requests. Only patients scheduled to see participating oncologists were approached. Patients were then mailed study information, and approached via telephone by a bilingual RA to confirm eligibility and obtain verbal informed consent. Upon verbal consent, patients were randomised 1:1 within their language group to either intervention or control (stratified by recruitment site and sex).

Participants completed a baseline questionnaire prior to their consultation. Once participants arrived in clinic for their consultation, written consent was obtained and those in the intervention group received a QPL in their own language. All participants then had their consultation audio-recorded using a Dictaphone. Immediately post-consultation, all participants completed a short follow-up questionnaire; and those randomised to the intervention group received a copy of their consultation audio-recording on a USB or CD. Two weeks after their consultation, all participants completed a semi-structured interview (SSI) on the telephone with a bilingual RA and a second follow-up questionnaire. Control participants did not receive a copy of the QPL and received their consultation audio-recording after completing the final questionnaire and SSI.

A free-call telephone number was set-up to allow participants to leave messages in their own language regarding any queries or concerns during the trial. Bilingual RAs checked the telephone message system daily.

5.2. Allocation concealment

Bilingual RAs were blinded to participant randomisation in order to minimise bias. Administration of the intervention (provision of QPL and consultation audio-recording) was conducted by the study project manager who was not blinded to randomisation outcomes. Analysis was conducted with de-identified data.

5.3. Translation

Participant documents including participant information and consent forms, and patient-reported outcome measures (PROMS) were translated into the LOTE by NAATI translators. A summary of the translation process for this project has been published elsewhere [20].

6. Data collection

6.1. Feasibility assessment measures

Table 1 outlines the study processes that were examined to meet each of the three feasibility objectives and the feasibility parameters that were considered acceptable for each process. Feasibility acceptability parameters were developed a priori.

6.2. Patient-reported outcome measures and qualitative interviews

The following patient-reported outcome measures were included to address the endpoints of the future RCT: Patient Satisfaction with Cancer Care Scale (PSCCS) [21], Supportive Care Needs Survey (SCNS-SF-R) [22], State-Trait Anxiety (STAI-6) [23]. Translations of these measures were tested in a phase I pilot study for face validity, appropriateness, and cultural sensitivity [14], and were included in this present study to test the feasibility of study design and procedures (objective 2). The telephone SSIs comprised two parts: 1) Questions to assess the future proposed primary outcome of information recall (these methods are described elsewhere [18]; 2) Questions asking participants to provide feedback on the communication intervention and trial participation, with these results reported elsewhere [24]).

6.3. Time and costing data

Relevant costings were calculated using the current award (and pro-rata hourly rate) for casual RAs in Australia. Specific activities were included in the costings calculations if they were common to all clinical research and may be impacted or lengthened due to migrant patient requirements.

7. Data analysis

Descriptive statistics were used to summarise feasibility data including screening and recruitment processes, design and procedures, and time and costing. Analyses were performed in Excel 2010 (Microsoft, Redmond, WA, USA), apart from interval estimations for binomial proportions which were estimated in R (reference index version 3.4.0) [25] using the Wilson method (confidence level: 95%) [26]; the ‘binom’ package was employed for this purpose [27].

8. Results

8.1. Objective 1. assessment of screening and recruitment processes

A total of 47 participants were recruited; 20 in the Mandarin language group, 10 in Cantonese, eight in Greek, and nine in Arabic. See Fig. 1 for CONSORT diagram, Table 2 for screening and recruitment rates, and Table 3 for demographic data. Overall, the acceptability parameters detailed in Table 1 (approach, consent, attrition rate) were not met for all groups as a whole, however, three of the four language groups did meet at least one individual parameter.

8.1.1. Arabic

Arabic-speaking patients did not meet the recruitment target, with only 9 patients recruited (45% of the target). Despite low numbers of potentially eligible patients (n = 25), 22 were approached (88%, 95% CI: 70%-96%), and almost half (9 of 19) of the confirmed eligible...
## Table 1
Data collection methods and acceptability parameters for the three feasibility objectives.

| 1. Screening and recruitment | Methods of data collection |
|------------------------------|----------------------------|
| Data collected               |                            |
| • Recruitment rates          | • Recruitment and withdrawal rates were collected using purpose-built screening and trial management databases |
| • Reasons for inclusion/exclusion of patients | • Any protocol deviations and additions to inclusion/exclusion criteria were logged |
| • Adherence and withdrawal rates for patients, oncologists, and interpreters | • |
| Acceptability Parameters:   |                            |
| Patient recruitment rates within each language group should meet the following minimums: | • ≥80% of identified eligible patients are approached |
| • ≥40% of patients consent to be part of the study | • ≤20% attrition rate |

### 2. Study design and procedures

| Data collected | Methods of data collection |
|----------------|----------------------------|
| Staff hiring and training | • Data on interpreter bookings and cancellations were collected including delays due to non-consented interpreters booked. |
| Interpreter bookings and cancellations | • Hospital consultation information was collected, including information regarding delays due to oncologist non-consent, cancellation, lack of clinical or interpreter availability, etc. Facilitators and barriers to intervention delivery, including effective trial procedures were recorded. |
| Oncologist barriers and facilitators and availability | • Additional unexpected events or feedback which arose as part of the trial were also logged in the trial management database. |
| Appointment delays | • Patients, oncologists, interpreters and other key stakeholders were encouraged to provide feedback. |
| Intervention delivery | • Specific attention/data logging was paid to the timing of these issues; in this case, whether they occur during study establishment or throughout the duration of the trial. |
| Any additional unexpected culturally-specific aspects arising as part of the trial | • |

Acceptability Parameters:
In terms of intervention fidelity and trial feasibility, acceptable minimums include:
• ≥95% of participants in the intervention group receive QPL and audio-recording of their hospital consultation,
• ≤10% of audio-recorded consultation bookings are cancelled,
• ≥90% of anticipated consultation audio-recordings completed within the 1st or 2nd consultation after participant’s consent

### 3. Time and costing

| Data collected | Methods of data collection |
|----------------|----------------------------|
| Time/cost of: |                            |
| • Recruitment | • Data were collected on time spent: screening (attending multi-disciplinary team meeting, reviewing patient electronic files and interpreter booking requests); patient approach; semi-structured interview; all additional patient contact; intervention delivery (audio-recording consultation, time spent in clinic waiting room); questionnaire delivery if verbal; transcription; review and translation of hospital consultations and semi-structured interviews; data entry and management; |
| • Intervention delivery | • |
| • Questionnaire delivery | • |
| • Translation and transcription | • |
| • Patient contact | • |
| • Data management | • |

### Patients’ consent

Patients who were approached consented to participate in the study (47%, 95% CI: 27%–68%). This cohort met the minimum acceptable attrition rate (11%, 95% CI: 2%–43%).

#### 8.1.2. Cantonese

Most of the eligible Cantonese-speaking patients were approached (90%, 95% CI: 77%–96%), however, only a small number met the eligibility criteria (n = 24). The consent rate, while meeting the target, was also low with 42% (95% CI: 24%–61%) of eligible patients consented. Only 10 of a target of 20 Cantonese patients (50%) were recruited in 10 months, with many patients declining due to lack of interest in the study (n = 8). This cohort did not meet the minimum acceptable attrition rate of ≤20%, (30%, 95% CI: 11%–60%), despite only three participants withdrawing due to appointment cancellations.

#### 8.1.3. Greek

The Greek language group did not meet any of the acceptability parameters for recruitment with only 75% (95% CI: 63%–85%) of potentially eligible patients approached, and only 25% (95% CI: 13%–42%) consenting to participate. There was also 25% (95% CI: 7%–59%) attrition. Most importantly, the recruitment target of 20 participants within 10 months was not met, with only eight patients recruited during the study period (40% of the target). The majority of Greek-speaking patients who declined did so due to lack of interest (n = 9), or family’s advice not to participate (n = 3).

#### 8.1.4. Mandarin

The Mandarin language group reached their recruitment target in approximately seven months; however, the acceptability parameter to approach at least 80% of potentially eligible patients was not met (76%, 95% CI: 62%–85%). Bilingual RAs were unable to approach some patients over the telephone (n = 5) due to ‘gate keeping’ by concerned family members, or due to time constraints (n = 6) between screening and scheduled appointments.

#### 8.1.5. Interpreter and oncologist recruitment

All approached oncologists consented to participate (n = 43). Some consented oncologists were audio-recorded on more than one occasion with different participants. All interpreters working regularly at both hospital sites were approached (n = 24). All of the interpreters who were approached consented, except for one Greek interpreter who declined due to discomfort being audio-recorded. Consented interpreters formed a ‘pool’ of interpreters who were prioritised or directly booked for consented patients’ appointments.

#### 9. Objective 2. assessment of design and procedures

Overall, feasibility parameters were met for both intervention fidelity and for consultation bookings, however only when re-scheduling and re-booking of administrative appointment cancellations was taken into account across all language groups. Staff hiring and training was determined to be feasible, with all staff successfully retained throughout the duration of the trial.
Fig. 1. CONSORT diagram for patient participants (numbers in brackets are listed by language group: Arabic, Cantonese, Greek, Mandarin).
project. Staff training (outlined in Table 4) was conducted to ensure that speaking, three Greek-speaking, two Mandarin-speaking; and four necessities that were necessary due to the migrant patient requirements came trial consent. However, while 100% of Mandarin, Cantonese and Greek anticipated bookings were captured within the 1st or 2nd booking from 31% of Arabic patients, 23% of Cantonese pa booking cancellations was set at the minimum accept 9.2. Intervention fidelity GCP standards were met, and that staff received constructive feedback. As noted in Table 1, the acceptability parameter for consultation booking cancellations was set at the minimum acceptability parameter of ≥95% of patients. Overall, 98% of patients received both the QPL and audio-recording; however, when reviewing by language group, delivery of the intervention to Arabic patients failed to meet the minimum, with only 89% of patients receiving both QPL and audio-recording, due to the Dictaphone failing in one appointment. The intervention was delivered to 100% of participants in all other language groups. 9.3. Consultation bookings and cancellations As noted in Table 1, the acceptability parameter for consultation booking cancellations was set at ≤10%. This standard was not met by any language group, as 31% of Arabic patients, 23% of Cantonese patients, 11% of Greek patients and 13% of Mandarin patients had their cancellations cancelled due to administrative reasons relating to appointment or interpreter booking changes unrelated to this study. Despite initial cancellations, almost all language groups were able to reschedule the consultation audio-recording to the next appointment. Overall, the minimum acceptability parameter was met, as ≥90% of anticipated bookings were captured within the 1st or 2nd booking from trial consent. However, while 100% of Mandarin, Cantonese and Greek patients had appointments booked successfully or rescheduled if needed, this was the case for only 78% of Arabic patients. 10. Objective 3. assessment of time and costing Time data were collected for all activities relating to recruitment, intervention delivery, patient contact, and data management (see Table 4). The costs associated with training the bilingual RAs in activities that were necessary due to the migrant patient requirements came to $11,192 (see Table 4). The time and costs associated with screening, recruitment, and data collection are included in Table 5. Notably, costs associated with approach and recruitment of patients who may not be eligible or decline to participate are important to record and consider. As noted in Table 1, no acceptability parameters were defined, as data was collected to provide a baseline estimate of costing, and to identify areas where costs can be reduced. 11. Discussion The focus of this project was to develop and test appropriate research methods for engaging migrant populations for future efficacy assessment of the INFORM communication intervention, a comprehensive package of cancer information and QPLs in Arabic, Cantonese, Mandarin and Greek, and an audio-recording of a key medical consultation. Assessment of key parameters comprising screening, recruitment, study design, procedures, time, and costing revealed that despite some barriers to achieving minimum criteria proposed, predominantly the methods utilised in this study supported the inclusion of migrant oncology patients in research. A future multi-site RCT efficacy assessment of the INFORM communication intervention using these methods may be feasible if steps are taken to strengthen screening and recruitment processes, as outlined further below and summarised in Table 6. 11.1. Screening and recruitment processes Importantly, only the Mandarin-speaking language group met all of the pre-specified recruitment criteria and targets. For Arabic, Cantonese, and Greek-speaking patients, consent rates ranged from 25 to 47%. These consent rates are much lower than the reported average in systematic reviews of clinical trial consent rates (>82%), although the numbers in this study are too low to make firm conclusions, they indicate a trend that migrant and refugee patients may be more hesitant about research participation [28,29]. Wariness or unfamiliarity about research and family concerns were common reasons for non-consent. While decision-making between taking part in a trial offering new treatment will differ from participation in psych-social interventions, differences in consent rates do highlight that cultural-specific barriers such as research unfamiliarity or family concerns are important to consider in research that includes migrant and refugee populations. Considerations regarding migrant and refugee patients’ familiarity with research processes, and general and health literacy will also factor into research participation and consent. Language and literacy can be significant barriers to recruitment if patients are unable to read participant information and consent forms [11,30]. Previous literature has highlighted many instances of cancer diagnoses being associated with stigma and negativity in some migrant communities, potentially impacting on willingness to engage with supportive care research [31,32]. Further, many cultural groups prefer to
engage in health decision-making as a family unit, or the family may make decisions on behalf of the unwell individual [33]. A consent process which focuses on the patient rather than the family—as is common in western research—would be considered potentially inappropriate and prohibitive to participation in this context. While this study employed a variety of methods to engage migrant and refugee patients, additional steps could be considered in addressing these identified barriers.

Table 3
Demographic data for all language groups.

| Variable                        | Arabic n = 10 | Cantonese n = 7 | Greek n = 6 | Mandarin n = 19 |
|--------------------------------|--------------|----------------|-------------|---------------|
| Age in years, mean (range)     | 53 (27-71)   | 57 (48-76)     | 74 (31-74)  | 61 (37-76)    |
| Country of Birth (n)           | Egypt (3)    | China (3)      | Greece (6)  | China (18)    |
|                               | Iraq (1)     | Hong Kong (2)  | Missing (1) |               |
|                               | Lebanon (1)  | Syria (2)      | Missing (1) |               |
| Cancer Type, n (%)             |              |                |             |               |
| Bone and soft tissue           | No (0)       | Yes (3)        | No (0)      | Yes (0)       |
| Brain                          | 3 (38)       | 0 (0)          | 0 (0)       | 0 (0)         |
| Gynaecology                    | 1 (13)       | 0 (0)          | 0 (0)       | 1 (5)         |
| Haem                           | 0 (0)        | 0 (0)          | 0 (0)       | 1 (5)         |
| Head and neck                  | 1 (13)       | 2 (29)         | 0 (0)       | 1 (5)         |
| Lower gastrointestinal         | 0 (0)        | 1 (14)         | 2 (33)      | 6 (32)        |
| Lung                           | 1 (13)       | 0 (0)          | 0 (0)       | 6 (32)        |
| Upper gastrointestinal         | 0 (0)        | 0 (0)          | 1 (17)      | 2 (11)        |
| Urology                        | 2 (25)       | 1 (14)         | 3 (50)      | 2 (11)        |
| Sex, n (%)                     | Male         | 2 (25)         | 6 (66)      | 4 (67)        |
|                               | Female       | 6 (75)         | 1 (14)      | 2 (33)        |
| Relationship Status, n (%)     | Single       | 0 (0)          | 0 (0)       | 3 (16)        |
|                               | Married/de facto | 6 (75)       | 2 (29)      | 0 (0)         |
|                               | Separated/divorced | 1 (13)      | 2 (29)      | 0 (0)         |
| Employment Status, n (%)       | Working      | 2 (25)         | 2 (29)      | 0 (0)         |
|                               | On sick leave | 1 (13)         | 1 (14)      | 0 (0)         |
|                               | Not employed  | 1 (13)         | 2 (29)      | 1 (17)        |
|                               | Retired       | 2 (25)         | 2 (29)      | 4 (67)        |
|                               | Home duties   | 1 (13)         | 0 (0)       | 0 (0)         |
|                               | Studying      | 1 (13)         | 0 (0)       | 0 (0)         |
|                               | Other         | 1 (13)         | 0 (0)       | 0 (0)         |
|                               | Missing       | 0 (0)          | 0 (0)       | 1 (17)        |
| Education Level, n (%)         | No formal schooling | 2 (25)      | 0 (0)       | 0 (0)         |
|                               | Primary school | 1 (13)        | 0 (0)       | 5 (83)        |
|                               | Secondary school | 1 (13)      | 4 (57)      | 0 (0)         |
|                               | Tertiary school | 4 (50)      | 3 (43)      | 0 (0)         |
|                               | Trade college  | 0 (0)          | 0 (0)       | 5 (26)        |
|                               | Missing       | 0 (0)          | 0 (0)       | 1 (17)        |
| Living Arrangements, n (%)     | By yourself/ independently | 0 (0)       | 0 (0)       | 3 (16)        |
|                               | With spouse/partner and children | 1 (13)     | 1 (14)      | 0 (0)         |
|                               | With children only | 5 (63)       | 4 (57)      | 3 (50)        |
|                               | Other         | 2 (25)         | 1 (14)      | 3 (50)        |
|                               | Speak English, n (%) | Yes         | 4 (50)      | 4 (63)        |
|                               | No            | 2 (25)         | 3 (38)      | 1 (17)        |
|                               | Self-reported English Proficiency, n (%) | Basic     | 1 (13)      | 2 (25)        |
|                               | Intermediate  | 5 (63)         | 2 (25)      | 1 (17)        |
|                               | Advanced      | 0 (0)          | 0 (0)       | 0 (0)         |

Table 4
Bilingual Research Assistant training and costing.

| Topic                          | Training type       | Time | Delivered by            | Costing (AUD) |
|--------------------------------|---------------------|------|-------------------------|---------------|
| Cancer Basics                  | Formal presentation | 4 h  | -Project Team           | $1456         |
| Research Methodology           | Formal group training| 4 h  | -Project Team           | $1456         |
| Trial methodology              | -Small group training sessions | Ongoing | Project Team | Included in RA wage/ general project expenditure |
| Good Clinical Practice         | Certified group     | 4 h  | Training Handbook       | $1456         |
| Informed consent,              |                     |      |                        |               |
| Ethics in Research             |                     |      |                        |               |
| Voluntary participation        |                     |      |                        |               |
| Confidentiality                | Conductor           |      |                        |               |
| Conducting patient consent     | Research peers      |      |                        |               |
| Research peers                 |                     |      |                        |               |
| Cultural awareness and         | Peer review         |      |                        |               |
| potential research barriers    |                     |      |                        |               |
| Role/Skills                    |                     |      |                        |               |
| Training                       |                     |      |                        |               |
| Boundaries when interacting    |                     |      |                        |               |
| with patients,                 |                     |      |                        |               |
| Good Clinical Practice         |                     |      |                        |               |
| Good Clinical Practice         |                     |      |                        |               |
| calls                          |                     |      |                        |               |
| Empathy,                       |                     |      |                        |               |
| Handling distress during a     |                     |      |                        |               |
| telephone call                 |                     |      |                        |               |
| Self-care                      |                     |      |                        |               |
| Qualitative interviewing       | -Multiple group     | 8 h  | -Project Team           | $2912         |
| Purpose                        |                     |      |                        |               |
| Training sessions (<3 h)       |                     |      |                        |               |
| Open/closed questions          |                     |      |                        |               |
| Probes versus leading questions|                     |      |                        |               |

(continued on next page)
11.2. Design and procedures

Formal appointment of consumer advocates from migrant communities at the outset of this study optimised the likelihood that culture-specific considerations were identified and integrated into the research design as appropriate [14]. Genuine consumer engagement with migrant patient communities has been shown to benefit recruitment and to improve the generation and dissemination of research outcomes [30,34]. Despite universally perceived institutional obstacles to migrant and refugee research [30], this trial demonstrated that engagement with relevant clinical and interpreter staff worked to overcome process barriers present in trialling this complex intervention. Unengaged clinicians can act as gatekeepers to clinical trial enrolment if not adequately briefed and involved in the research process [35].

Bilingual populations are essential for conducting research with migrant populations who are non-fluent or not literate in dominant languages [31,34]. Notably, prioritising bilingual staff who have research experience is not always necessary [34], as research training can be provided. This trial demonstrated that brief, intensive and regular research training, in combination with peer review and feedback, were effective in training research-naïve, bilingual health and translation workers to conduct robust research. While recruitment of bilingual RAs is not feasible or necessary in every research study, our results suggest that hiring and training of such staff to cover dominant languages of the region (other than national language spoken) can be effective and manageable.

The INFORM communication intervention was successfully integrated into a busy clinical setting. However, findings demonstrated that technical difficulties, such as the Dictaphone failing, impacted on intervention delivery. Other technological solutions such as smartphone apps for audio-recording consultations may be more feasible [36,38].

11.3. Time and costing

Research with migrant patients does accrue additional costs. More support is needed to facilitate participation in research-related activities, particularly when patients have low literacy in their own language [37]. However, our trial has shown that these costs, once itemised, are not overwhelmingly large. Once researchers become familiar with the processes and procedures needed to include migrant groups in clinical research, research with these groups will become progressively easier and less costly, as the necessary infrastructure (in terms of staffing, training and resources) is established.

11.4. Limitations and future research

While valuable data were collected on the feasibility of research within migrant populations using this study design, it is acknowledged that only two hospital sites in an urban setting within the same state in Australia were included, with only four language groups participating. Future studies could test the recommendations from this trial in mainstream clinical research.

12. Conclusion

Many trials exclude migrant patients due to concerns regarding

Table 5: Assessment of time and costing of project-related activities.

| Variables: n, (range), AUD, hours:minutes:seconds | Screening and interpreter contacts | Mandarin |
|-------------------------------------------------|-----------------------------------|----------|
| AU, hours:minutes:seconds                        | All patients                      |          |
| Arabic                                          | 38 56 43 33                       |          |
| Cantonese                                       | 6:20:00 9:20:00 7:2:00 5:30:00    |          |
| Greek                                           | 31 52 77 37                       |          |
| Greek                                           | 7:12:00 12:24:00 12:11:00 8:45:00|          |
| Mandarin                                       | 12:48:00 20:03:00 20:40:00 14:00:00|          |
| Arabic                                         | 494 760 798 532                   |          |
| Cantonese                                       | 760 798 532 532                  |          |
| Greek                                           | 184 161 84                       |          |
| Mandarin                                       | 12:48:00 20:03:00 20:40:00 14:00:00|          |
| Arabic                                         | 47 44 18 74                      |          |
| Cantonese                                       | 47 44 18 74                      |          |
| Greek                                           | 46 44 39 113                     |          |
| Mandarin                                       | 15:30:00 17:30:00 13:06:00 15:30:00|          |
| Mandarin                                       | 608 568 532 532                 |          |
| Mandarin                                       | 171 93 100 217                   |          |
| Arabic                                         | 19 9(–33) 10 (2–16) 13 (7–20) 11 (3–24)|          |
| Cantonese                                       | 21 14 11 42                      |          |
| Greek                                           | 3 (0–9) 2 (1–4) 2 (1–4) 3 (0–10) |          |
| Mandarin                                       | 40 38 20 66                      |          |
| Arabic                                         | 5 (1–9) 4 (3–5) 3 (0–4) 4 (1–7) |          |
| Cantonese                                       | 13:15:00 11:24:00 7:34:00 20:39:00|          |
| Mandarin                                       | 13:15:00 11:24:00 7:34:00 20:39:00|          |
Summary of recommendations.

1. Identify and address cultural-specific barriers faced by different groups such as:
   - Structural issues such as racism, lack of cultural safety
   - Familiarity and trust with research and research processes
   - General literacy and health literacy (in their own language)
   - Cultural stigma/taboo relating to the health condition
   - Consent processes (e.g. involving or not involving family)

2. Formal appointment of consumer advocates from the specific cultural communities you are wishing to engage with to:
   - Advise on research design and processes
   - Assist with above identification of cultural-specific barriers
   - Provide input on trial-related challenges from the relevant patient/cultural perspective

3. Hiring Bilingual Research Assistants
   - Conducting research processes with patients in their own language is necessary to ensure participant safety and understanding
   - Brief, intensive research training is effective in upskilling healthcare and/or skilled interpreting and translation workers in the delivery and management of research

Importantly bilingual staff will also be adept at identifying and addressing cultural-specific barriers faced by participants

4. Ensure research trials/grant applications include appropriate funding for migrant participants
   - Research with migrant patients does accrue additional costs; these should be clearly documented as essential components of research design and processes
   - These costs will reduce over time as the necessary infrastructure and human resource is established

Grants should better facilitate allocation of funds to support research with migrant participants

additional costing, staffing and time. It is hoped that learnings from this trial will assist future research with inclusion of migrant participants. The feasibility of a future RCT testing implementation of consultation recordings and question prompt lists into clinical care for migrant patients would need to strengthen screening and recruitment processes to ensure adequate sampling to support efficacy testing.

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Ethical approval

Peter MacCallum Cancer Centre HREC approval no.: 14/145.

Clinical trial registration

This study was registered prospectively with the: Australia and New Zealand Clinical Trials Registry (Trial ID: ACTRN12616001538437).

Transparency declaration

This manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

Availability of data and material

All data requests relating to the trial should be made to psc.hofield@swin.edu.au.

Consent to participate and publish

All participants provided written and verbal informed consent in their own language (Arabic, Greek, Mandarin and Cantonese) to participate in the study, and have their non-identifiable data published as part of standard research dissemination practices.

Author contributions

PS, PB, MJ and TH conceived the study. AH and KG prepared the study protocol, and worked with RLS to adapt the design to a hospital setting, undertake analysis and write the manuscript. RLS and AH and EZ and SW were involved in data collection. RLS and KG contributed to the data analysis and interpretation. KG, PB, MJ, TH, SH, EZ, SW, UO and PS were involved in revising the article critically and contributing important intellectual content. PS is the guarantor.

Declaration of interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The authors declare the following financial interests/personal relationships which may be considered as potential competing interests:

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