Chapter II:

The ASPIRE evaluation
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2.1 Introduction

Ageing-in-place as a model aims is to facilitate older people remaining living in the community for as long as possible, with residential care entry being delayed until the older person's needs can no longer be safely met in the community. The individuals in the ASPIRE study are older people who have been assessed as having high (Support Needs Level 4) or very high and complex needs (Support Needs Level 5) which put them at risk of residential care entry. The individuals receiving community support packages from the ageing-in-place Initiatives (AIPI) will be compared to older people receiving NASC determined services or residential care. To demonstrate the effectiveness of the AIPI, both the quality of care and the cost of care must be examined. If the cost of care is decreased, but the level of quality in care delivered is less, then the AIPI is not a viable alternative for long-term care delivery. If the level of quality increases and the cost of care is significantly higher in the AIPI, then the AIPI may not be an affordable option for long-term care for funders to consider. It is also important for the study to consider the effects of AIPI on the primary informal carer, normally a spouse.

A randomised control trial is the best approach for measuring the effectiveness and cost-effectiveness of ageing-in-place initiatives for the following reasons.

1. Allow direct comparison between the AIPI and conventional health care delivery
2. Produce study groups that are comparable with respect to known and unknown confounding factors
3. Remove investigator (selection) bias in assignment of older people to AIPI or conventional health services
4. Guarantee that statistical tests will have valid significance levels (Weinberger, Nagle et al. 1994)

A randomised controlled trial generates evidence typically classified as Level II as illustrated in Table 2-1. However, ASPIRE is a pooling of the randomised controlled trial evaluation of three ageing-in-place initiatives, or in other words, a meta-analysis. Because meta-analyses draw on different datasets, they generate highly reliable results and as a
consequence, the findings arising from ASPIRE can be considered as a minimum of Level II evidence.

Table 2-1: Level of evidence (modified from NHMRC, 2000)

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Study design</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Evidence obtained from a systematic review (meta analysis) of all relevant randomised controlled trials</td>
</tr>
<tr>
<td>II</td>
<td>Evidence obtained from at least one properly-designed randomised controlled trial</td>
</tr>
<tr>
<td>III-1</td>
<td>Evidence obtained from well-designed pseudo randomised controlled trials (alternate allocation or some other method)</td>
</tr>
<tr>
<td>III-2</td>
<td>Evidence obtained from comparative studies (including systematic reviews of such studies) with concurrent controls and allocation not randomised, cohort studies, case-control studies, or interrupted time series with a control group</td>
</tr>
<tr>
<td>III-3</td>
<td>Evidence obtained from comparative studies with historical control, two or more single arm studies, or interrupted time series without a parallel control group</td>
</tr>
<tr>
<td>IV</td>
<td>Evidence obtained from descriptive studies e.g. case series, either post-test or pre-test/post-test designs</td>
</tr>
</tbody>
</table>

The study is administered and managed by Auckland UniServices Ltd a wholly owned company of The University of Auckland; the conduct is supervised by the ASPIRE operations team, a group of researchers experienced in clinical trials and medical research.

2.2 Ageing-in-place initiatives to be evaluated in this study

The combined and individual effectiveness were examined in the following services:

- The Coordinator of Services for the Elderly (COSE) model in Christchurch.
- The Presbyterian Support Northern (PSN) Community F.I.R.S.T. (Flexible Integrated Rehabilitation Support Team) model in Hamilton
- The Wellington Masonic Villages Promoting Independence Programme (PIP) in Lower Hutt
2.2.1 The usual care (Control) group

Services available to older people assessed with high and complex needs are numerous and include primary care (e.g. GP, Practice Nurses, Pharmacists), Disability Support Services (e.g. NASC, Home Care and Residential Care, Respite, Caregiver support), Health services (e.g. Geriatrician, Therapy, District Nursing), Community services (e.g. Lions, Rotary), Consumer groups (e.g. Age Concern, RSA) Regional council services (Citizen's Advice Bureau, Housing), ACC (Tai Chi and Otago Exercise Programme), WINZ (Household support and funding).

Services such as these vary considerably according to geographical location and therefore usual care similarly varied across the three DHB regions. However, although there was considerable commonality, the unique features of the AIPI meant that what was delivered in usual care differed in certain key areas according to what services the AIPI offered or replaced.

COSE, in Canterbury as already discussed is an evolution of traditional NASC services and replaces NASC. Therefore, the usual care group includes NASC and is in direct comparison with COSE (The AIPI). However, both groups share all other services as described above. For instance older people randomised to the AIPI group would receive the same home care services or residential services as those randomised to the usual care group.

The Masonic PIP model is an ‘additional’ service to what is normally offered to older people and does not replace any services. PIP represents a slow stream rehabilitation service offered through residential care for a limited period of time and upon discharge home, the team provide education to the traditional home care service and enhanced case management. Older people in the usual care group however, would have been discharged directly to either their home or permanently to a residential home. The same NASC workers operate across the intervention and usual care group.

Community FIRST is an example of restorative home support and replaces traditional home care for older people and offers an alternative to residential care for older people choosing to remain living at home. NASC services are the same across usual care and AIPI and as the Community FIRST is funded through a bulk funding arrangement, other
aspects that would normally be funded through NASC are covered by this arrangement, such as caregiver residential respite and day care.

2.3 Study aims

The aim of this study is to assess the effectiveness and cost-effectiveness of ageing-in-place initiatives in assisting older people with high and very high needs to remain living in the community, preventing or delaying entry into permanent residential care and reducing mortality. This project seeks to evaluate the effectiveness and cost-utility of the following AIPI; the Presbyterian Support Community FIRST model operating in Hamilton, the Masonic PIP model in Lower Hutt and the COSE model in Christchurch.

2.4 Study objectives

1. To assess the effectiveness of AIPI, as compared to conventional home-based care in preventing (or delaying) the time before a community-based older person requires permanent residential care

2. To assess the effectiveness of AIPI in improving survival in community-based older people compared to conventional care

3. To determine the impact of the AIPI on an older person's independence and health-related quality of life compared to similar measures in those receiving conventional care

4. To establish the degree of correlation between the expected improvement in the health-related quality of life of informal caregivers attributable to AIPI, in comparison to those receiving conventional care

5. To determine the cost-effectiveness of AIPI to the client, family, providers and funding agency in relation to the conventional care model

6. To identify the key elements of the AIPI healthcare models of community-based service delivery that lead to beneficial outcomes

2.5 Study design

2.5.1 Participating centres

AIPI in Hamilton, Lower Hutt and Christchurch are being evaluated using three separate randomised controlled clinical trials. Hamilton and Lower Hutt are models to improve the functional status (or independence) of older people and Christchurch is a case
management intervention. In Hamilton and Lower Hutt, the study population were recruited from older people who were being referred to a needs assessment and service co-ordinator (NASC). Randomisation occurred at the individual level, or in other words, every time an older person consented to enter the trial they were randomised to either AIPI or usual care. In Christchurch, General Practitioner practices were randomised to either receive a COSE case manager or usual care (standard hospital based NASC). The service that the older person received was dependent on which arm of the trial their GP was randomised to; COSE or usual care (standard NASC). On completion of the study, the three groups were pooled for analysis.

2.5.2 Criteria for eligibility

All older people who were referred to a NASC co-ordinator in Hamilton, Lower Hutt and Christchurch and who were under the care of a General Practitioner or a Geriatrician, were potentially eligible for inclusion in this study if they met the following criteria: These criteria were inclusive of the criteria for the AIPI being evaluated. Or in other words, the ASPIRE criteria matched the normal service eligibility criteria. The purpose for this is to ensure that ASPIRE mimics normal every day service activities rather than introducing a ‘true’ experiment and in doing so allows the findings to be more readily generalised to the wider population of older people.
Inclusion criteria

1. Males and females aged 65 or greater years on the day of baseline examination or 55+ Maori or Pacific Island or classified by NASC as ‘like age and interest’

2. All participants are assessed by the NASC co-ordinators or hospital clinicians as meeting the classification of High\(^2\) or very High\(^3\) (complex) health and disability needs

3. All participants or their main caregiver must provide and be capable of providing a declaration of ‘Informed Consent’

4. All participants must be English-speaking or provide a family member who can act as an interpreter

Exclusion criteria

If participation in the programme, in the opinion of the multi-disciplinary team, meant that there was an unacceptably high risk to the older person remaining at home, with multi-disciplinary care, such as high risk of injury from falls.

2.5.3 Study interventions

There are three models of AIPI that are being evaluated, namely:

- The Presbyterian Support Northern (PSN) Community F.I.R.S.T. (Flexible Integrated Rehabilitation Support Team) model in Hamilton
- The Masonic Promoting Independence Programme in Lower Hutt
- The Coordinator of Services for the Elderly (COSE) model in Christchurch

\(^2\) High needs: The older person's ability to remain in their environment is compromised due to significant safety issues and complex support needs. Outcome: The older person has access to a safe environment and effective support; the carer has access to meaningful and practical support, enabling them to maintain their life roles; specialised assessment and treatment services are accessed; the carer is valued and supported. (Ministry of Health, 2002)

\(^3\) Very High Needs: Due to rapid deterioration the older person's support needs have significantly increased; current support is no longer effective; the safety of the older person and carer is at risk. Outcome: The older person is sustained by a support package; the carer is sustained by a support package; areas requiring specialist attention are addressed, i.e. reversibility and rehabilitation; longer term planning is underway (Ministry of Health, 2002)
2.5.4 Recruitment strategies

Community FIRST, Hamilton and Masonic PIP, Lower Hutt

1. Following NASC assessment and confirmation of entry criteria and needs level being confirmed as high or very high, the older person was asked whether they were interested in a person from The University of Auckland coming to speak to them about an evaluation of health services.

2. If yes, NASC contacted the local research associate with older person contact details.

3. If no, NASC collected demographic information.

4. The research associate contacted and visited the older person and their caregiver to provide information and obtain consent.

5. If yes to consent, research associate undertook baseline assessment of older person. The research associate left the questionnaires for the primary informal caregiver to complete for baseline assessment.

6. If no, research associate requested demographics.

7. The research associate undertook randomisation on their laptop computer.

8. The research associate contacted NASC within a maximum of 24 hours of first contact to inform them which service the older person had been allocated to (new service or usual care).

Figures 2-1 and 2-2 highlight the recruitment process employed in the ASPIRE study for Hamilton and Hutt respectively.
Figure 2-1: Hamilton recruitment process
Figure 2-2: Hutt Valley recruitment process
The COSE initiative, Christchurch

1. General Practices were randomised to receive either a COSE worker (1 COSE worker per 3000 older people (Greater than or equal to 65 years) living in the area or to receive NASC co-ordinated services

2. Any older person assessed by NASC or COSE as meeting entry criteria was asked if they were interested in a person from The University of Auckland speaking to them about an evaluation of health services

3. If yes, NASC or COSE contacted the local research associate with the older person's contact details

4. If no, NASC or COSE collected demographic information

5. Research associate contacted and visited older person and caregiver to provide information and obtain consent

6. If yes to consent, the research associate undertook baseline assessment of older person. The research associate left the questionnaires for the primary informal caregiver to complete for baseline assessment.

7. If no, research associate requested demographics

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4. The older person continued to receive NASC or COSE services if they refused participation in the ASPIRE study
Figure 2-3: Christchurch recruitment process
2.5.5 Randomisation assignment

Randomisation with equal probability to each of the trial arms was undertaken. A minimisation design was employed in Hamilton and Hutt whereby older people were stratified according to:

- Disability (high or very high health and disability needs);
- age (below 74 years, 75 years and above);
- gender (male or female) and;
- living situation (living alone or with others).

This process meant that an equal balance of factors (variables) known to influence outcomes were balanced between randomised groups, thereby increasing the reliability of the study detecting a true effect of the AIPI services on outcome. For example, there were very similar numbers of males in the Masonic PIP programme in Lower Hutt as there were in the usual care group. This method is often used in studies that have smaller sample sizes as seen in the Hamilton and Lower Hutt sites; as if this process was not followed, an imbalance of certain variables such as gender may occur.

Christchurch employed a more complex randomisation process (block randomisation) as it was not possible to randomise at the point of NASC assessment as COSE workers were attached to G.P. practices. Therefore, the older person’s place of residence informed which group they would be assigned to. Consequently, two randomisation processes were utilised as described below.

Community First, Waikato and the Masonic Slow Stream Rehabilitation, Lower Hutt

Every older person was individually randomised by the research associate through a software programme installed on laptop computers. Minimisation methods were achieved through daily uplink to the Clinical Trials Research Unit server system.

Coordinator of Services for Elderly (COSE), Christchurch

COSE workers were assigned to G.P. practices according to a stratified cluster randomisation process and individual older people had their randomisation status pre-
assigned according to whether or not they were registered with a COSE-G.P. (active) or NASC-G.P. (control). Consent to participate as an active or control participant meant consent to participate in an evaluation of health outcomes over two years.

2.6 Outcome measures

The follow-up period lasted an average of 18 months. Data were collected at baseline, three, six, 12, 18 and 24 months post-randomisation. Please see Table 2-2 for the investigation schedule. The data were collected by research associates within each site.

2.6.1 Primary end-points

- Combination of either death or permanent residential home admission

2.6.2 Secondary end-points

- Survival
- Permanent residential home admission
- Disability
- Quality of life
- Number of acute hospitalisations
- Number of falls
- Social support network
- Health-related quality of life of the primary informal caregiver
- Experience of the primary informal caregiver
- Costs (direct and indirect)

Tertiary end-points

- Predictive modelling
### Table 2-2: Investigation schedule

<table>
<thead>
<tr>
<th>Time (month)</th>
<th>T₀</th>
<th>T₃</th>
<th>T₆</th>
<th>T₁₂</th>
<th>T₁₈</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Older person</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Demographics</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MDS-HC</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Social Networks</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>EuroQoL 5D</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Caregiver</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CRA</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>SF36</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>EuroQoL 5D⁵</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
</tbody>
</table>

#### 2.6.3 Outcome measures of the older person

Survival is defined as the amount of time a participant lives, from registration until the time of death. The date of death was collected from the health service provider by the research associate. Administrative staff in each site also surveyed local newspapers for death notices and in addition, further confirmation was ascertained by access to various national datasets on completion of the study.

The entry of the older person into permanent residential care required the approval from the DHB and the notification of the NASC co-ordinator. Entry of the older person into permanent residential care was confirmed by the research associate contacting the NASC co-ordinator on a regular basis and further confirmation was ascertained using the national CCPS dataset on completion of the study.

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⁵ The EuroQoL 5D is completed by the caregiver, but is the caregiver’s perception of the quality of life of that older person at that point in time. It is not a reflection of the caregiver themselves.
The Minimum Data Set – Home Care (MDS-HC)

InterRAI, a United States (US) based not-for-profit organisation with membership from notable international gerontologists and clinicians, has developed and implemented a range of assessment tools for older people. The tools are now being widely utilised in the US, the United Kingdom (UK) and Canada as well as six DHBs across New Zealand\(^6\). Following a systematic review of the literature on comprehensive assessment instruments as part of the NZ Guidelines Group’s development of Guidelines for Assessment Processes for Older People, consideration is being given to the adoption of the InterRAI assessment tools within New Zealand. The first MDS assessment instrument to be developed was the MDS-RAI instrument for nursing homes. The MDS-RAI was developed in the USA and InterRAI has since developed other instruments for the assessment of older people in a variety of settings:

- MDS-Acute Care (MDS-AC)
- MDS-Post Acute Care (MDS-PAC)
- MDS-Palliative Care (MDS-PC)
- MDS-Mental Health (MDS-MH)
- MDS-Home Care (MDS-HC)
- MDS-Self-reliance screener (MDS-Screener)

InterRAI (Carpenter et al, 2002) reports that all the tools have significant benefits in that:

(a) they facilitate the consistent and comprehensive assessment of older people;
(b) the use of the tools support assessors to consider the whole person;
(c) that care is based on accurate, reliable information;
(d) the results of the assessment assist clinicians in identifying problems and potential for improvement and;
(e) that interdisciplinary staff involvement in assessment and care planning is improved. Further, the data arising from the assessment facilitates the monitoring of indicators of quality of care, which in turn allows for evaluation of impact on case mix and resource management, and clinical effectiveness.

\(^6\) Waikato, Bay of Plenty, Hutt Valley, Capital and Coast and Canterbury DHBs are all using the MDS-HC as part of a trial implementation of the tool in New Zealand. The University of Auckland are involved in a MoH funded evaluation.
Services such as those being evaluated under ASPIRE often have numerous impacts on older people with complex needs and it was identified as extremely important that as much information as possible would be collected from the older person and their caregiver. Normal research practice until recently has been to utilise multiple tools to assess function, cognition, quality of life, satisfaction as well as a host of other areas. Even with this approach, there remains a distinct risk that important areas will be missed. Therefore, for the purposes of the ASPIRE study, the MDS-HC\(^7\) was adopted as the main assessment outcome tool. All MDS-HC assessments in the ASPIRE study were undertaken by a research associate, of whom all were experienced health professionals, trained specifically in the use of the MDS-HC. The MDS-HC is a comprehensive assessment instrument which allows assessment of multiple key domains such as function, health, social support and service use (Morris, 1996). Summary scales have been derived from the MDS items and validated in comparison with widely-accepted instruments (Mor et al. 1997; Hawes et al. 1995; Hartmaier et al. 1995). The scales explore each older person’s performance in basic and instrumental activities of daily living and in cognitive function (cognitive performance scale). The validity & reliability of MDS-HC is well-documented and is included in table 2-3 (Morris, Fries et al. 1997). Some of the studies that validate the scales against established scales use the scales within the MDS-RAI (Residential Assessment Instrument) and not the MDS-HC. However, the MDS-HC was developed as an extension of the MDS-RAI and the items have been shown to be equally applicable to the home care environment (Morris, Fries et al. 1997).

All research associates were trained in the use of the assessment tool and inter-rater reliability of assessments were established.

\(^7\) The ASPIRE study utilised the MDS-HC (version 2.03) measurement tool (UK Version)
### Table 2-3: Summary of MDS-HC outcome scales validation

<table>
<thead>
<tr>
<th>Outcome Scales</th>
<th>Validated Against</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activities of Daily Living scales (short &amp; long forms)</td>
<td>Reliability (Morris, Fries et al. 1999) Barthel Index Scale (Landi, Tua et al. 2000)</td>
</tr>
<tr>
<td>MDS ADL Self-Performance Hierarchy Scale</td>
<td>Reliability (Morris, Fries et al. 1999)</td>
</tr>
<tr>
<td>The MDS Depression Rating Scale</td>
<td>15-item Geriatric Depression Scale (Burrows, Morris et al. 2000)</td>
</tr>
<tr>
<td>IADL Difficulty Scale and IADL Involvement Scale</td>
<td>Not validated</td>
</tr>
<tr>
<td>Changes in Health, End-stage disease and Signs and Symptoms (CHESS)</td>
<td>Compared CHESS score against survival time (Hirdes, Frijters et al. 2003)</td>
</tr>
<tr>
<td>Pain Scale</td>
<td>Visual Analogue Scale (Fries, Simon et al. 2001)</td>
</tr>
</tbody>
</table>

The MDS-HC has various scales embedded within as listed below and described in full in Appendix II.

- ADL Self-Performance Hierarchy Scale
- ADL Short Form Scale
- ADL Long Form Scale
- Instrumental activities of daily living (IADL) scales
- IADL involvement Scale
- The Cognitive Performance Scale (CPS)
- Depression Rating Scale (DRS) (Burrows et al, 2000)
- Changes in Health, End-stage disease and Signs and Symptoms (CHESS
- Pain Scale for the Minimum Data Set
- Index of Social Engagement (ISE)
Social support network

Social support network and network type of the older person is being ascertained by the use of the Practitioner Assessment of Network Type (PANT) instrument (Wenger 1994). Wenger has defined five different support network types and the differences between them are associated with the presence and availability of local close family, the frequency of interaction within the networks and the degree of involvement within the community (Wenger 1991). There is no evidence of validation or repeatability for this instrument. Wenger is currently validating the PANT instrument in a large study. The existence of the network typology constructed by Wenger has been independently verified by Litwin (2001).

Hospital admissions

The number of hospital admissions including visits to the emergency department will be obtained from the AIPI service provider and the DHB for 6 months before and 12 months after study entry. Encrypted NHI numbers will be used to access costs. The number of falls will be recorded into the MDS-HC by the research associate.

2.6.4 Outcome measures of the primary informal caregiver

The primary informal caregiver is defined as an adult family member, or another individual, designated by the older person as taking responsibility for their Health and Safety. Questionnaires for the primary informal caregiver are left with the caregiver at the older person’s residence to complete and to return by post in a prepaid envelope to The University of Auckland.

*Medical Study Short Form (SF36®)*

The Health related quality of life of the primary informal caregiver is being measured by the Medical Study Short Form (SF-36®) (Ware and Sherbourne 1992). This questionnaire is a single multi-item scale that assesses eight health concepts: physical limitations caused by health problems, limitations in social activities caused by physical or emotional problems, role limitations caused by physical health problems, and emotional problems, bodily pain, general mental health, vitality and general health perceptions. The SF-36 has been tested
extensively for reliability and validity (McHorney, Ware et al. 1992; Ware and Sherbourne 1992; McHorney, Ware et al. 1993; McHorney, Ware et al. 1994).

Figure 2-4 illustrates the taxonomy of items and concepts underlying the construction of the SF-36 scales and summary measures. The eight scales are hypothesized to form two distinct higher-ordered clusters due to the physical and mental health variance that they have in common.

**Caregiver Reaction Assessment (CRA)**

The experience of the primary informal caregiver with health services, including perceived carer stress, is being measured by the Caregiver Reaction Assessment (CRA) Instrument (Given, Given et al. 1992). The CRA assesses specific aspects of the care giving situation, including both negative and positive dimensions of care giving reactions. The CRA contains 24 items and factor analysis provides five subscales, namely, caregiver's esteem, lack of family support, impact on finances, impact on schedule and impact on health. Respondents use a five-point Likert scale. CRA has been used and validated with caregivers of older people with physical impairments, and Alzheimer's disease and with caregivers and partners of cancer patients (Given et al. 1992; Nijboer, Triemstra et al. 1999). The CRA was chosen for this study, as it has been utilised in caregivers of older...
people with both physical and mental impairments and addresses the positive aspect of care-giving. Table 2-4 highlights this tool.

Table 2-4: Caregiver Reaction Assessment Instrument

<table>
<thead>
<tr>
<th>Item</th>
<th>Question</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>*I feel privileged to care for ___.</td>
</tr>
<tr>
<td>2.</td>
<td>Others have dumped caring for ___ onto me.</td>
</tr>
<tr>
<td>3.</td>
<td>*My financial resources are adequate to pay for things that are required for care giving.</td>
</tr>
<tr>
<td>4.</td>
<td>My activities are centred around care for ___.</td>
</tr>
<tr>
<td>5.</td>
<td>Since caring for ___ it seems like I'm tired all of the time.</td>
</tr>
<tr>
<td>6.</td>
<td>It is very difficult to get help from my family in taking care of ___.</td>
</tr>
<tr>
<td>7.</td>
<td>I resent having to take care of ___.</td>
</tr>
<tr>
<td>8.</td>
<td>I have to stop in the middle of work.</td>
</tr>
<tr>
<td>9.</td>
<td>*I really want to care for ___.</td>
</tr>
<tr>
<td>10.</td>
<td>My health has gotten worse since I've been caring for ___.</td>
</tr>
<tr>
<td>11.</td>
<td>I visit family and friends less since I have been caring for ___.</td>
</tr>
<tr>
<td>12.</td>
<td>*I will never be able to do enough care giving to repay ___.</td>
</tr>
<tr>
<td>13.</td>
<td>*My family works together at caring for ___.</td>
</tr>
<tr>
<td>14.</td>
<td>I have eliminated things from my schedule since caring for ___.</td>
</tr>
<tr>
<td>15.</td>
<td>*I have enough physical strength to care for ___.</td>
</tr>
<tr>
<td>16.</td>
<td>Since caring for ___, I feel my family has abandoned me.</td>
</tr>
<tr>
<td>17.</td>
<td>*Caring for ___ makes me feel good.</td>
</tr>
<tr>
<td>18.</td>
<td>The constant interruptions make it difficult to find time for relaxation.</td>
</tr>
<tr>
<td>19.</td>
<td>*I am healthy enough to care for ___.</td>
</tr>
<tr>
<td>20.</td>
<td>*Caring for ___ is important to me.</td>
</tr>
<tr>
<td>21.</td>
<td>Caring for ___ has put a financial strain on the family.</td>
</tr>
<tr>
<td>22.</td>
<td>My family (brothers, sisters, and children) left me alone to care for ___.</td>
</tr>
<tr>
<td>23.</td>
<td>*I enjoy caring for ___.</td>
</tr>
<tr>
<td>24.</td>
<td>It's difficult to pay for ___, health needs and services.</td>
</tr>
</tbody>
</table>

Coding Scheme:

1.  =  Strongly disagree
2.  =  Disagree
3.  =  Neither agree nor disagree
4.  =  Agree
5.  =  Strongly agree

* These questions are reverse scored.
2.7 Determination of the cost-effectiveness of AIPI and conventional health services

In addition to determining whether the AIPI has resulted in improved health status among the targeted populations, the study also seeks to ascertain whether the initiatives represent good value for money. This is an essential component of the evaluation as it speaks to the issue of whether the initiatives are sustainable in the long run. There are several possible outcomes. For instance, the initiatives could result in improved health outcomes and reduced costs. This would be the best possible outcome as it would suggest the initiatives are both technically and allocatively efficient. Another possibility is that the initiatives result in better health outcomes, but at an additional cost to one or more of the parties (e.g., health services, families or caregivers). In this event, the health gains must be placed in some context that enables decision and policy-makers to ascertain whether the gains justify the additional expense.

The cost-effectiveness analysis examines both the cost and health outcomes from the AIPI and conventional services. The work will include:

- Identifying the average and marginal cost of providing the services at the locations,
- Identifying the direct and indirect costs associated with the initiatives and with standard care,
- Identifying the cost-effectiveness of the initiatives.

NOTE. The results of this analysis will form the basis of a further report and will not be included in this document.

2.8 Older People Entering Residential Accommodation (OPERA)

OPERA is a sub-study of ASPIRE and focuses on the qualitative aspects of residential home admission. The objectives of the OPERA study were to explore, describe and interpret:

- the factors which led the older person to enter residential care;
- who were the decision-makers for the residence of the older person;
- the older person’s feelings about the residence decision (either residential care, or their own home).
The study was conducted in two phases: pilot and the main study. Both involved semi-structured interviews of older people (and their caregivers where possible) who had recently been assessed as needing high or very high levels of support. This level of support was consistent with the requirements for entry to residential care.

2.8.1 Pilot study

The pilot, consisting of 13 older people and who were not part of the ASPIRE study included interviews with six people who had recently been admitted to residential care, six primary caregivers, a Needs Assessment Service Co-ordination team (N.A.S.C.), and a multi disciplinary hospital based team (MDT). Data gathering was undertaken through interview using a set of open-ended questions with only pre-arranged prompts being given when necessary, which decreased the likelihood of any potential biases. The interview with the older person and caregiver lasted approximately 45 minutes and were related to the older person’s residence decision, the processes and the support available to them. The interview questions with the NASC, and MDT were general questions concerning who made the decisions regarding the residence of an older person and their processes for the decision. Also included were questions regarding residence decisions in regard to some specific older people.

2.8.2 Main study

The main study, consisting of 131 older people who were all enrolled in the ASPIRE study, included a total of 28 participants who were interviewed in residential care, with the remainder being interviewed at home. The participants where possible, had two interviews at an interval of six months. Also interviewed were 24 caregivers and an NASC team who discussed 12 of the older people recently admitted to residential care. The main study participants were invited to participate from the ASPIRE trial in the three centres, Hamilton, Lower Hutt and Christchurch. The interviews were carried out face-to-face in residential care, and in the older person’s home, or by telephone. A sequential mixed methods study for data collection was selected for this phase because of the multiple approaches to data collection, analysis and inferences employed in the sequence of events. Data arising from the audio-recorded interviews were transcribed verbatim to ensure accuracy of intent.
A general inductive approach methodology was used throughout with the intention of:

(a) finding common themes from the pilot, to use in the development of the questionnaire for the main study and;

(b) forming an understanding of the factors and decision makers for the residence decision, and the older person's ultimate satisfaction with that decision.

The qualitative data analysis programme QSR NVivo was used to unitise and categorise the data. This process facilitated the development of ‘meta-themes’ representing the range of experiences described within the study. Inter-rater reliability was tested by transcripts being given to two independent senior researchers to code. The codes were compared and discussed. Four different triangulation types were used to strengthen this study as follows:

1. data triangulation; data from a variety of different people,
2. investigator triangulation, where several different researchers were used,
3. theory triangulation, where the data was looked at from multiple perspectives within the ASPIRE trial and the OPERA study; and
4. methodological triangulation using both qualitative and quantitative methods

2.9 Ethical considerations

Ethical approval was granted from the lead ethics committee (Auckland) and was submitted to the ethics committees in Hamilton, Lower Hutt and Canterbury in July 2003 (Reference No: AKX/03/07/177) and for OPERA as an amendment to the ASPIRE trial by the lead Ethics Committee, Auckland on the 14th October 2004 (AKX/03/07/177 PIS/Con V#2,5/09/03). Approval for the trial was also gained from the managers of NASC and providers. Informed consent was gained by a signed consent from the older people and caregivers. Confidentiality and anonymity was maintained at all times.

2.10 Adverse event reporting

All of the older people enrolled in this study were under the clinical care of their G.P. and the health services being evaluated. The trial was evaluating health services; therefore the intervention does not directly increase the risk of adverse events. If the research associate found during the collection of data that the older person required medical or social assistance, then she notified the ASPIRE project manager who immediately notified the
health service. In emergency situations, the research associate called an ambulance and notified the ASPIRE project manager. However, adverse events may result due to the health service itself, and as such under Adverse Effect (AE) and Serious Adverse Effect (SAE) definitions, processes have been adopted to ensure that such events are monitored in an appropriate manner.

2.10.1 ASPIRE interim reporting

At six monthly intervals throughout ASPIRE, the study statistician and Associate Professor Philippa Poole, Faculty of Medical and Health Sciences, The University of Auckland reviewed the un-blinded adverse event data from the study. Professor Poole is an independent medical clinician with extensive experience in geriatrics. Adverse events which were reviewed included:

- Death
- Life threatening events
- Permanent or substantial injury
- Unplanned hospitalisation or prolongation of hospitalisation
- Falls with serious injury resulting in medical attendance by a GP or Hospital
- Medically important illnesses were coded as infectious, cardiovascular, orthopaedic, neuro-psychiatric or other

All treatment comparisons were performed by intention to treat\(^8\) and by trial and then pooled in a meta-analysis. Any differences between treatment groups for these outcomes were deemed to reach statistical significance if the p-value was less than 0.003 or 3 standard deviations. Additional data that was monitored included the rate of the primary end-point of institutional-free survival in the control group and the coefficient of variation of true proportions between clusters within each group (k) in the Christchurch study. These two measures have been estimated to be 0.35 and 0.3, respectively, in the sample size

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\(^8\) a type of analysis of clinical trial data in which all patients are included in the analysis based on their original assignment to intervention or control groups, regardless of whether participants failed to fully participate in the trial for any reason, including whether they actually received their allocated treatment, dropped out of the trial, or crossed over to another group.
calculation. Consideration has been given to increasing the sample size if the control rate of institutional-free survival is lower than 0.35 or if \( k \) is greater than 0.3.

On the basis of the results of each interim analysis, Professor Poole had the ability under the respective Ethical Committees to advise the trial operations committee to continue on as previous for the proceeding six months, or contact the DHB to modify the health service or consider stopping the delivery of the health service, or modify the study protocol or stop the evaluation. During the course of the study, there was no reason for Professor Poole to contact the Operations Committee to modify the service.

### 2.11 Study definitions

#### 2.11.1 Institutionalised-free survival

Institutionalised-free survival will be defined as participants without permanent admission into residential care or death from the Date of Assessment. Therefore institutionalised-free survival is defined as the number of days from the randomisation date until either of permanent residential care admission or death, whichever is come first.

\[
\text{Time to Death or permanent residential care} = (\text{Date of the Death}, \\
\text{Date of permanent residential care admission minus Date of Randomisation})
\]

#### 2.11.2 Participant withdrawal and lost to follow-up

A withdrawal is defined as a withdrawal of consent to participate post-randomisation. Lost to follow-up is defined as participants who were alive at their last contact, but have became unavailable for further contacts. The Research Associates will request the opportunity to ask some questions on a six-monthly basis to ascertain if they are alive and where they are living. The older person or primary informal caregiver has the right of refusal. Participants who withdrawal / lost to follow-up from the study will be assumed to be censored unless the death of participants are confirmed.
2.11.3 Censoring date

If the participants are still alive at the end of study then the censoring date is the date that study ends. If the subjects are withdrawal or lost to follow-up the censoring date is the date of last contact. Censoring date is not applicable to subjects who died or entered into permanent residential care. Censoring days (only for subjects who are event free) is defined as:

(Date of last contact or Date of the study ends Date of Randomisation)

2.11.4 Changes from Baseline

Absolute change from Baseline is defined as:

(Post Baseline Value – Baseline Value)

2.12 Statistical issues

2.12.1 Sample size and cluster size calculations

The ASPIRE meta-RCT design provides an efficient way to evaluate the effects of the AIPI models of care on a substantive outcome that would not be possible in a single RCT. Consideration was given to running a single, multi-centre trial; however this was not feasible for two main reasons. Firstly, the interventions in each of the centres are similar but not the same. Secondly, it is not feasible to randomise individuals in Christchurch hence GP practices will form the units of randomisation in Christchurch. Standard criteria and measures will apply across all trials so it is anticipated that heterogeneity will be kept to a minimum. The following sample size calculation is based on the meta-RCT.

A total sample size of 830 patients provides a power of 90% with a two-sided $\alpha = 0.05$ to detect a 30% relative risk reduction in the primary end-point of institutional-free survival between groups, assuming 35% frequency of death or residential care in controls. A total sample size of 830 would also provide almost 80% power to detect a 25% relative risk reduction. This sample size is sufficient to allow analysis of effects of the different AIPI on secondary and tertiary endpoints as well as the primary endpoint. 830 subjects from three
trials equates to 277 from each trial. However, the 277 subjects required in Christchurch needs to be increased to take account of the clustering. To do this some assumptions are required.

Since Christchurch centre had a randomisation allocation at the GP level, 55 GPs were randomly assigned to one of the 2 intervention groups and all older people within each GP received the same intervention. Typically, individuals within a Practice are more similar than those from different Practices. In statistical terms, observations within a cluster are correlated and this lack of independence must be taken into account when it comes to analysing the data. This is commonly referred to as a design effect (DEFF) and will almost always be greater than 1 indicating that more patients are required to effectively achieve the same sample size as that from the standard trial, which randomises at the patient level. As explained above, the DEFF increases as the within-cluster correlation and the number of participants within a cluster increase. For example when Design Effect equal 2, has double the variance and half the effective sample size compared to the study without clustering.

For the purpose of the setting the total sample size to allow 90% Power when all 3 centres are combined, we have assumed that the DEFF is equal to 2 (cluster size=11, ICC=0.1). This gives us the anticipated total sample size required of 1109 patients.

2.12.2 Amendments to the protocol

Sample size was revised several times, on the basis of event rates also revised due to inappropriate assumptions on initial statistical tests. Throughout the study, the event rate was periodically monitored in order to revise the sample size for the study. Survival models (exponential and weibull) were applied to time-to-event data to estimate the 18 month institutionalised-free survival rates.

The estimated parameters were then used to predict event rate at the end of study. The general study design, and analysis approaches remained unchanged. The schedule of visits was changed to Baseline, 3-months, 6-months (short version), 12-months and 18-months. As a consequence of time and financial considerations, it was decided to end recruitment short of the target sample size.
2.12.3 Statistical analysis

Procedures of the statistical analysis system SAS (SAS Institute Inc. Cary NC) SPLUS and Acluster software was used in all analysis. All statistical tests were two-tailed and a 5% significance level maintained throughout the analyses. It is generally considered that a 5% level of significance is of statistical interest and was employed in ASPIRE. However, more pertinent to the real life evaluations is a level that can describe a clinical difference (e.g. moving from a participant requiring supervision with meal preparation ‘score 2’ on the ADL scale to setup help only ‘score 1’). Despite this, clinical significance is often difficult to delineate. Stratford et al (1996) stress that clinical significance can be likened to “beauty” in that “clinical significance is often unique to the beholder” (pg. 1119). McMurdo and Rennie (1994) when investigating the influence of exercise on institutionalised frail older people concluded that a 10% improvement in flexibility or handgrip strength is of clinical interest. Nonetheless, researchers would agree (Stratford et al, 1996) that patients, practitioners and economics all feasibly play a defining role. This pertinent issue will be discussed further in the chapters III and IV.

All treatment evaluations were performed on the principle of ‘Intention to Treat’. No adjustments for multiplicity were undertaken for the secondary endpoints, adverse events, or other endpoints. The study design of ASPIRE was to combine three trials by using Meta-analysis to give an overall treatment effect across centres. The study was powered based on the Meta-analysis, and not on any of the individual trials alone. However, analysis proceeded initially by exploring each centre separately and then pooling the results together. The principle of Meta-analysis is to increase power to detect an overall treatment effect as well as investigate the amount of variability between studies.

2.12.4 Reporting of intra-cluster correlation coefficient (ICC)

As the Intra-cluster correlation coefficient plays a key role in any clustered randomised trial, it is essential to estimate the ICC, to allow for clustering in the analysis, as well as report as outlined in the extension to the consort statement. There are many methods available to estimate ICC, however, for the purposes of this study, ANOVA was employed to estimate ICC (Shrout and Fleiss, 1979). In addition, this result was confirmed by utilising the
A cluster software, which is the software for design and analysis of clustered randomised trials (Donner, 2000) (See Appendix 1 for more information).

### 2.12.5 Primary endpoint

As defined above, institutional-free survival was the primary outcome for this analysis. Participants could only experience the primary outcome once. The impact of treatment on binary time-to-event outcomes was determined using standard log rank survival tests and adjusted analyses were performed when imbalances in important baseline characteristics were observed. As there were several variables that were believed to contribute to survival, a Multivariate Cox Proportional Hazards Model approach was used. When the Hazard Ratio (HR) is greater than 1, it means the hazard of new service is greater than the usual care. Or in other words, if the HR = 1.50, then the hazard of the new service is 1.5 times higher compared to the usual care. Or one can say that the chance of reaching the primary endpoint (residential home admission or death) is 50% higher in the new service compared to the usual care. Hazard Ratio analysis was also employed to explore the relationship between various variables and residential home admission and death.

Stratification Factors (age, sex, needs level and home alone) was also included in the incorporate model together with treatment effect. A Meta-analysis was then used to pool the Hazard ratios from three centres to provide an overall estimate.

### 2.12.6 Secondary endpoints

Ninety-five percent confidence intervals with no adjustment for multiple comparisons were calculated and will be presented for all secondary outcomes. Confidence intervals provide a range in which the true value is likely to occur 95% of the time, which is better than reporting P values that relate to a single test. Secondary outcomes such as MDS Scale measurements, Quality of Life, Acute Hospitalisation and falls are measured at the baseline, 3-month, 6-month, 12-month and 18-month. Analysis on secondary outcomes will be undertaken according to two scenarios:

1. **Partial dataset (removing data after an older person has entered residential care):**
   This allows for an exploration of the impact of Community FIRST and PIP in
comparison to usual home based services. It has disadvantages in that if one group has more observation points than the other (i.e. if there is an imbalance in the admission to permanent residential care between the groups) then the results are based on a smaller sample size.

2. Complete dataset (including data after an older person has entered residential care)

This approach draws on more data as all subjects are included and therefore results are more statistically sound.

Both methods have a role in interpreting the findings and both will be presented and scenario 2 is used for subgroup analysis. Summary statistics (i.e. mean, standard deviation, n, or median, inter quartile range [IQR]) on baseline data and follow-ups will be showed in findings and in Appendices where relevant.

The total number of follow-up assessments was dependent on when an older person was registered into the study, whether the person died, the date of their last visit, and whether they were lost to follow-up before the end of the study. Therefore, the number of visits with measurements on the secondary endpoints varied across participants. As well as for many participants, data were missing for other reasons, e.g. incomplete assessment made. Thus, to properly carry out an Intention to Treat (ITT) analysis, we will need to deal with missing data. A mixed model with repeated measures will be used to allow every participant to be included in the analysis, and allow estimation of the treatment effect on each of the secondary endpoints.

To allow for correlation between measurements at different time periods on the same participant, covariance pattern models will be considered. There are 8 common Covariance Pattern includes Unstructured, First Order Autoregressive, Compound Symmetry, Toeplitz, Heterogeneous Uncorrelated, Heterogeneous Compound Symmetry, Heterogeneous First Order Autoregressive and Heterogeneous Toeplitz. However, only the first four covariance patterns will be tested in the analysis. Different covariance patterns will be tested to choose the appropriate covariance pattern. Likelihood ratio tests or AIC can be used for statistical comparisons between models.
2.12.7 Subgroup analysis

Subgroup analyses were conducted on data categorised according to Needs Level (High or Very High), CHESS score, age group (65-75, 75-85, 85+), Sex, Ethnicity, presence or absence of dementia and have/not have caregiver if data is permitting. Centre analysis was performed at the subgroup level and then pooled by the Meta-analysis as described above.

2.12.6 Per-protocol data set

A per-protocol analysis was also performed in order to check the robustness of the results if more than 5% cross-over cases in the study was identified.

2.12.9 Missing values and outliers

Missing data on primary outcome should not be permitted, as the information on primary end-points are obtainable by using hot-pursuit case finding method (i.e. Death Certificate, Institutionalisation records of residential care). Outlying observations in the data set were identified and clear identification of an outlying observation was made on the basis of clinical as well as statistical grounds. A sensitivity analysis was performed in order to assess the impact of outlying observations. Handling of missing data for the secondary endpoints was handled via the use of mixed modelling techniques as described above.

2.12.10 Predictive modelling analyses

Hazard Risk Ratios estimates were calculated and adjusted for age, sex, ethnicity and treatment effect with 95% Confidence Intervals and p-values for both Residential Care Entry and Hospitalisation as the Primary end-points. The technique is described above. A risk with predictive modelling is to introduce error by excessive searching for risk factors. Bland and Altman (1995, pg. 170) argue that a large number of statistical tests are difficult to interpret

“...because if we go on testing long enough we will inevitably find something which is significant. We must be aware of attaching too much importance to a
lone significant result among a mass of non-significant ones. It may be the one in 20 which we would expect by chance alone."

Thus, a more sensible approach is to use literature to inform the search analysis pathway. Hirdes et al (2004) developed the Home Care Quality Indicators (HCQI) as a means to assess quality of home based organisations and further to introduce the potential to benchmark services. The HCQI are drawn from pertinent scales and questions in the MDS-HC and utilise CAPS in order to gather benchmarking information around the service. In short, the HCQI are new tools providing a first step along the path of quality improvement for home care. These indicators can provide high-quality evidence on performance at the agency level and on a regional basis. The HCQI (Table 2-5) were used for predictive modelling analysis in ASPIRE and in addition, the EuroQoL VAS and Caregiver Reaction Assessment summative scores were used.
Table 2-5: Inter-RAI Home Care Quality Indicators for Minimum Data Set—Home Care Version 2.0

<table>
<thead>
<tr>
<th>HCQI</th>
<th>Numerator</th>
<th>Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence HCQIs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Inadequate meals</td>
<td>Clients who ate ≤1 meals in 2 of last 3 days</td>
<td>All clients</td>
</tr>
<tr>
<td>Weight loss</td>
<td>Clients with unintended weight loss</td>
<td>All clients, excluding clients with end-stage disease on initial assessment</td>
</tr>
<tr>
<td>Dehydration</td>
<td>Insufficient fluid intake</td>
<td>All clients</td>
</tr>
<tr>
<td>No medication review by MD</td>
<td>Number of clients whose medications have not been reviewed by a physician within last 180 days</td>
<td>Clients who are taking at least 2 medications</td>
</tr>
<tr>
<td>Difficulty in locomotion and no assistive device</td>
<td>Clients with impaired locomotion who are not using assistive device</td>
<td>All clients with impaired locomotion on most recent assessment (excludes clients for whom indoor locomotion did not occur)</td>
</tr>
<tr>
<td>ADL/rehabilitation potential and no therapies</td>
<td>Clients are not receiving OT, PT, or exercise therapy</td>
<td>Clients who trigger CAP for ADL/rehab potential</td>
</tr>
<tr>
<td>Falls</td>
<td>Number of clients who record a fall on follow-up assessment</td>
<td>All clients not completely dependent in bed, mobility on previous assessment</td>
</tr>
<tr>
<td>Social isolation with distress</td>
<td>Clients who are alone for long periods of time or always and they also report feeling lonely or clients who are distressed by declining social activity</td>
<td>All clients</td>
</tr>
<tr>
<td>Delirium</td>
<td>Clients with sudden or new onset/change in mental function or clients who have become agitated or disoriented such that their safety is endangered or client requires protection by others</td>
<td>All clients</td>
</tr>
<tr>
<td>Negative mood</td>
<td>Any client with sad mood on most recent assessment and at least 2 symptoms of functional depression are exhibited up to 5 days/week or daily or almost daily</td>
<td>All clients</td>
</tr>
<tr>
<td>Disruptive/intense daily pain</td>
<td>Clients having daily pain and intense pain or pain disrupts activities</td>
<td>All clients</td>
</tr>
<tr>
<td>Inadequate pain control</td>
<td>Clients who have pain and are receiving inadequate pain control</td>
<td>All clients having pain on most recent assessment</td>
</tr>
<tr>
<td>Neglect or abuse</td>
<td>Clients who have unexplained injuries, have been abused or neglected</td>
<td>All clients</td>
</tr>
<tr>
<td>Any injuries</td>
<td>Clients with fractures or unexplained injuries</td>
<td>All clients</td>
</tr>
<tr>
<td>No flu vaccination</td>
<td>Clients who have not received influenza vaccination within the last 2 years</td>
<td>All clients excluding clients receiving chemotherapy/radiation therapy</td>
</tr>
<tr>
<td>Hospitalisation</td>
<td>Clients who have been hospitalized, visited hospital emergency department, or received emergent care since last assessment</td>
<td>All clients</td>
</tr>
</tbody>
</table>
### Table 2-5: Inter-RAI Home Care Quality Indicators for Minimum Data Set—Home Care Version 2.0 (continued)

<table>
<thead>
<tr>
<th>HCQI</th>
<th>Numerator</th>
<th>Denominator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to improve/incidence HCQIs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bladder incontinence</td>
<td>Clients who have experienced decline in bladder cont. performance between previous and most recent assessment or clients who have developed new bladder cont. problem</td>
<td>All clients with at least one reassessment</td>
</tr>
<tr>
<td>Skin ulcers</td>
<td>Clients with ulcer on previous assessment who did not improve or clients with new ulcer on follow-up</td>
<td>All clients with at least one reassessment</td>
</tr>
<tr>
<td>ADL impairment</td>
<td>Clients with some impairment on ADL Long Form who failed to improve between previous and most recent assessment or clients who have new ADL impairment based on ADL Long Form</td>
<td>All clients with at least one reassessment who are not palliative on initial assessment</td>
</tr>
<tr>
<td>Impaired locomotion in home</td>
<td>Clients who fail to improve in locomotion in home or clients who have new impairment in locomotion in home</td>
<td>All clients with at least one reassessment who are not palliative on initial assessment</td>
</tr>
<tr>
<td>Cognitive function</td>
<td>Clients who have experienced decline in cognitive performance between previous and most recent assessment or clients who experience new cognitive impairment</td>
<td>All clients with at least one reassessment</td>
</tr>
<tr>
<td>Difficulty in communication</td>
<td>Clients with both failure to improve in communication/making self understood and failure to improve in ability to understand others or clients with new difficulties in making self understood or understanding others</td>
<td>All clients with at least one reassessment</td>
</tr>
</tbody>
</table>

### 2.13 Summary

ASPIRE is a large and complex study aimed to fully explore the impact of the new ageing-in-place initiatives on a host of outcomes for the older person and their informal caregiver. In essence, ASPIRE consists of three smaller evaluations of which when drawn together (meta-analysis) becomes a very powerful means to fully explore the impact of services and indeed ageing in a group of frail older people.