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## **BMJ Open**

## Evaluating an acute geriatric community hospital for older adults in a prospective cohort study compared with two historical control groups: a study protocol

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5	34	readmissions, functional decline.
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## 53 Abstract

*Introduction:* Hospital admission is associated with unwanted outcomes like readmission,
institutionalization, functional decline, and mortality in older adults with multiple chronic conditions.
Providing acute care in the community and integrating effective components of care models might
lead to a reduction of negative outcomes. Recently, the first geriatrician-led care Acute Geriatric
Community Hospital (AGCH) was introduced in the Netherlands. Care at the AGCH is focused on:
treatment of acute disease, comprehensive geriatric assessment, setting patient-led goals, early
rehabilitation and stream-lined transitions of care.

*Methods and analysis:* This prospective cohort study compared with two historical control groups will investigate the effectiveness of care delivery at the AGCH on patient outcomes, by comparing AGCH patients to hospital patients. Propensity score matching will correct for potential population differences. The primary outcome is the three month unplanned readmission rate. Secondary outcomes include: functional decline, institutionalization, healthcare utilization, occurrence of delirium or a fall, health-related quality of life, mortality and patient satisfaction. Measurements will be conducted at admission, discharge and one, three and six months after discharge. Furthermore, an economic evaluation and qualitative process evaluation to assess facilitators and barriers for implementation is planned.

*Ethics and dissemination:* The study will be conducted according to the Declaration of Helsinki. The
Medical Ethics Research Committee (METC) confirmed that the Medical Research Involving Human
Subjects Act did not apply to this research project and official approval was not required. The
findings of this study will be disseminated through academic and public lectures, scientific
conferences and in peer-reviewed journals. Furthermore, the findings of this study will aid in the
implementation and financing of this concept (inter)nationally. *Trial Registration Number* NL7896; pre-results

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2 3	79	Strengths and limitations of this study:
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6	80	- The strengths of this proposed study include: a mixed-methods evaluation of hospital, patient-
7 8	81	reported and economic outcomes; aiming to evaluate this complex intervention versus care as .
9 10	82	usual.
11	83	- Further strengths involve including patients and informal caregivers in the design, financing and
12 13	84	implementation of the Acute Geriatric Community Hospital.
14	85	Limitations associated with the design include: selection of appropriate controls from the two
15 16	86	historic cohorts, potential follow-up response rates to the questionnaires (conducted by
17	87	telephone), organizational challenges on chart review and collecting data on readmissions.
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31 32	94	telephone), organizational challenges on chart review and collecting data on readmissions.
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1 2		
3 4	108	Introduction
5 6 7	109	Background
8 9	110	Throughout the western world, there is an increase of older adults requiring acute care. Inpatient
10 11 12	111	services are mostly consumed by those over the age of 65. <sup>1,2</sup> The Netherlands, like many other
12 13 14	112	countries, recently (2015) implemented stay-at-home policies leading to an increase of frail older
15 16	113	persons living longer in the community. <sup>3</sup> These reforms juxtaposed with an increased aging
17 18	114	population, contribute to increased acute care utilization. <sup>4</sup> There has been a 19% increase in
19 20 21	115	emergency department visits by Dutch older adults based on data from 2015 versus 2017. <sup>5,6</sup>
22 23	116	Many older adults come to the hospital with complex and atypical health problems. <sup>5,7</sup> When older
24 25	117	persons are subsequently hospitalized, health outcomes are known to be poor, <sup>8</sup> particularly in
26 27 28	118	patients with geriatric syndromes such as cognitive impairment or mobility impairment. <sup>9,10</sup> For
29 30	119	example, previous research showed that 30% of older persons gained new disabilities and 20% were
31 32 33	120	readmitted within 30 days postdischarge. <sup>11,12</sup> Hospitalization itself may contribute to these poor
33 34 35	121	outcomes as hospital older adult inpatients often have reduced mobility while bedbound for
36 37	122	approximately 20 hours daily. <sup>13,14</sup> Low physical activity, in combination with poor nourishment and
38 39	123	increased caloric demand due to acute illness can lead to loss of muscle mass and may contribute to
40 41 42	124	the development of new disabilities, particularly in frail patients. <sup>15,16</sup> Together with noise in a hospital
43 44	125	environment and different personnel rotating through patient rooms, this contributes to sensory
45 46	126	overstimulation and sleep deprivation, which may lead to confusion and the occurrence of
47 48	127	delirium. <sup>17,18,19</sup> Not only is the patient affected during hospitalization, informal caregivers also find
49 50	128	hospital admissions stressful. <sup>20</sup> Furthermore, previous research showed that lack of discharge
51 52 53	129	planning in the hospital can result in the care needs of patients being unmet. <sup>21</sup> Hospital care as usual
54 55	130	compared to discharge planning and follow-up showed an increased on early readmissions. <sup>22</sup>
56 57 58 59 60	131	Readmissions can further effect patients recovery and increase healthcare costs. <sup>23</sup>

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2 3	422	
4	132	The complex medical needs of older persons, combined with their more dependent social situation
5 6	133	requires care delivery that offers guidance and support of realistic health and life goals. <sup>24</sup> Perhaps a
7 8	134	'gap' exists between what care can be provided in hospital, that is specialist care, with a focus on
9 10 11	135	medical treatment and diagnostics, versus what can be provided in the community, that is primary
12 13	136	care focused on rehabilitation, nursing care and wellbeing.
14 15 16	137	Several alternative strategies to hospital admission and (nurse-led) intermediate care have been
17 18	138	developed in the past as a substitute to conventional hospitalization. <sup>25</sup> Examples include (nurse-led)
19 20	139	intermediate care and subacute geriatric care units, low-tech but with geriatric expertise. <sup>26,27</sup> In
21 22 23	140	general, these types of care have comparable outcomes to hospital care as usual. Moreover, nurse-
24 25	141	led care in the US, observation units and hospital at home care all showed a cost reduction compared
26 27	142	to care as usual. <sup>25,26</sup> Until recently, the Netherlands however, had limited alternatives to
28 29 30	143	hospitalization for older persons who required acute care. Therefore, our research group sought to
30 31 32	144	create an acute care alternative and opened the Acute Geriatric Community Care Hospital (AGCH) in
33 34	145	July 2018, partnering with an academic hospital, an insurance company and a home care agency.
35 36	146	This acute geriatric care unit, which is based within an intermediate care facility, provides an
37 38	147	alternative to conventional hospitalization and delivers acute care closer to home.
39 40 41 42	148	The AGCH delivers hospital care that is focused on early mobilization and rehabilitation. Older
42 43 44	149	persons with common medical problems (such as urinary tract infections, pneumonia or heart
45 46	150	failure) and geriatric syndromes requiring hospital admission can be admitted to the AGCH. The
47 48	151	AGCH provides a form of intermediate care between primary and secondary care. In the Netherlands,
49 50	152	primary care includes general practice, community nursing and (temporary) admission to nursing
51 52 53	153	home. Secondary care includes medical specialist care and hospital admission. Care is supervised by a
54 55	154	geriatrician and provided by nurses trained in geriatric care who have experience as either a hospital
56 57 58	155	or community nurse. The rooms are designed to accommodate respite for the informal caregivers.
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2 3 4	156	Our hypothesis is that with the provision of integrated medical and nursing care close to home, the
5 6	157	AGCH is better suited to the needs of older adults with multiple chronic conditions and will lead to
7 8	158	better patient health outcomes and reduced post-acute care costs. Therefore, this study is designed
9 10	159	to compare care provided for older patients in the AGCH versus care provided in a hospital setting.
11 12 13	160	Specifically we aim to:
14 15 16	161	> Evaluate the 90-day readmission rate of patients acutely admitted to AGCH compared to
17 18	162	patients admitted a traditional hospital (usual care). Secondary outcomes include: functional
19 20	163	decline, institutionalization, healthcare utilization, the occurrence of geriatric syndromes such
21 22	164	as delirium, health-related quality of life, mortality, and patient satisfaction;
23 24 25	165	Assess the cost-effectiveness of the AGCH versus usual care by performing an economic
26 27	166	evaluation from a health care provider and societal perspective;
28 29	167	Conduct a process evaluation using interviews with key stakeholders to identify facilitators
30 31	168	and barriers to the implementation of the AGCH.
32 33	169	
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36 37	170	Methods
38 39 40	171	Setting
41 42	172	The Acute Geriatric Community Hospital opened in July 2018. It serves both the south-eastern part of
43 44	173	Amsterdam and its surrounding areas (an area with approximately 147 500 inhabitants). <sup>28</sup> The AGCH
45 46	174	is a 20 -bed facility within an skilled nursing facility. The hospital has 24-hour geriatric and nursing
47 48 49	175	assistance, physiotherapy and routine laboratory testing during the workweek and simple x-ray
50 51	176	available once a week. The population that is eligible for admission to the AGCH includes patients
52 53	177	with 1) acute medical problems requiring hospitalization (e.g. pneumonia, exacerbation of heart
54 55	178	failure or an urinary tract infection) 2) geriatric conditions (e.g. delirium, cognitive impairment, falls,
56 57 58	179	functional impairment), who are 3) hemodynamically stable and 4) not in need of complex diagnostic
59 60	180	testing. In general, patients will not be admitted if they: 1) require care that can only be provided at

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an intensive care unit 2) require surgery 3) require urgent treatments or diagnostic tests that can only be provided in-hospital (e.g. endoscopy, interventional radiology) 4) do not need hospital care, but require transfer to a skilled nursing facility and 5) live in another region of the Netherlands. Patients are directly admitted to the AGCH from the emergency department (ED) of the Amsterdam UMC- location Academic Medical Centre (AMC) in Amsterdam which is a 1000-bed academic hospital with approximately 30,000 ED visits yearly. After the on-call geriatrician has assessed that patient is eligible for AGCH admission and the patient or representative has agreed to admission, the patient is transferred to the AGCH by ambulance. Patients are admitted between 8.00 am and 11.00 pm, 7 days a week. At admission, a Comprehensive Geriatric Assessment (CGA) is conducted.<sup>29</sup> The CGA gives an overview of all medical, functional, psychological and social problems that are discussed during multidisciplinary team meetings and are used to formulate a care plan for each patient. 

## 193 Study design

This study is a prospective, observational, cohort study with two historical control groups to evaluate the clinical and economic effects of the AGCH. The STROBE statement was used in preparing the study protocol.<sup>30</sup> Participants will be compared to hospital controls. The participants are recruited into the study and are assessed at admission, discharge, one month, three and six months after discharge. The recruitment phase of this study started in February 2019. We plan to recruit for 18 to 24 months. The first three months of data collection will consist of a piloting phase to assess the feasibility of data-collection and follow-up. Moreover, we will assess the level of implementation of the AGCH care program alongside our investigation (see box 1). In addition, a qualitative process evaluation for the study on facilitators and barriers of the implementation of the AGCH will be conducted. 

## 206 Participants

Patients admitted to the AGCH are eligible for inclusion to the study. However, patients are excluded from the study if: 1) the attending physician judges that the patient is too ill to participate e.g. is terminally ill 2) the patient or legal representative does not consent to participate. 3) the patient or legal representative does not speak or understand Dutch or English. In the case of cognitively impaired or delirious patients, patients can only be included if a legal representative consents to participation and participates on their behalf. Cognitive functioning or the presence of delirium is assessed by the attending physician and confirmed by the researcher by conducting a Mini Mental State Exam (MMSE). A MMSE score of 15 or less Indicates severe cognitive impairment, in which the approval of a legal representative will be sought.<sup>31</sup>

## 217 Historical control groups

The first control group from the Transitional Care Bridge Study consists of 674 patients that were
recruited between September 2010 and March 2014 originating from the greater Amsterdam area in
the Netherlands.<sup>32</sup> Participants were patients of 65 years and older admitted for at least 48 hours to
an internal medicine ward. Proxy consent was provided for participants suffering from severe
cognitive impairment: Mini Mental State Exam<sup>31</sup> (MMSE) ≤15. They participated in a negative
randomized controlled trial that assessed the effectiveness of a nurse-led transitional care program
in preventing functional decline.<sup>32</sup>

The second control group (Hospital-ADL study<sup>10</sup>) consists of 401 patients that were recruited
 between October 2015 and June 2017 also originating from the greater Amsterdam area. These
 participants were enrolled in a prospective cohort studying the trajectory of functional decline in
 older hospitalized adults. Participants were aged 70 years and older, hospitalized for at least 48
 hours. Patients suffering from severe cognitive impairment (MMSE ≤15) and delirium were excluded
 from participation.

2 3 4	231	Patient and public involvement		
5 6 7	232	Older persons living in the Amsterdam area were involved in the design of the AGCH concept. There		
, 8 9	233	was no patient involvement in the design of this study.		
10 11	234			
12 13 14 15 16	235	Outcomes		
	236	The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.		
17 18 10	237	Secondary outcomes measured at 1,3 and 6 months will include:		
19 20 21	238	1) ADL-functioning as defined by the KATZ-ADL scale. <sup>33</sup>		
22 23	239	2) Healthcare utilization, including institutionalization in a long-term care facility.		
24 25	240	3) Occurrence of delirium and/or falls.		
26 27	241	4) Health-related quality of life (HRQoL). <sup>34</sup>		
28 29 30 31 32	242	5) All-cause mortality.		
	243	6) Satisfaction of patients and primary care givers with the care provided.		
33 34	244			
35 36 37 38	245	Data collection		
39 40 41 42 43 44 45 46 47	246	Eligible patients and/or legal representatives will be contacted and informed about the study		
	247	procedures after which written informed consent is obtained. Inclusion and interviewing of patients		
	248	is conducted by an onsite researcher. Routine data on functioning and risk assessments are collected		
	249	by a trained registered nurse and physiotherapist as part of the CGA for each patient. <sup>35</sup> Table 1 gives		
48 49	250	an overview of measurement of primary and secondary outcomes over time. Measurements during		
50 51 52 53 54 55 56 57	251	admission are at H1 which is within 48 hours after admission and H2 which is within 48 hours before		
	252	discharge. Follow-up is completed by telephone at 1,3 and 6 months after discharge (P1, P3 and P6).		
	253	Data collection includes:		
58 59 60	254	1. Medical and demographical data		

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Sociodemographic data. These will include age, gender, highest level of education, ethnicity, marital
status and living arrangement.

257 Time spent at the ED, admission diagnosis, date and time of admission.

258 *Chronic conditions.* The number and severity of chronic conditions will be assessed using the Charlson

259 Comorbidity Index.<sup>36</sup> This index is commonly used to indicate the risk of mortality; each condition is

scored 1, 2, 3 or 6 points, with a higher total number of points indicating a greater risk at death.

261 *Polypharmacy.* Polypharmacy will be assessed by counting the number of individual drugs that are

chronically prescribed to a participant, in which a number of 5 or more drugs is considered

263 polypharmacy.

264 *Mortality.* This will assessed during follow-up, where possible by reporting from patients electronic
 265 files, otherwise from registries of the general practitioner.

266 2. Cognitive functioning.

Cognitive impairment. This will be is assessed by reviewing the score of the Mini Mental State Exam
 (MMSE) that is performed within 48 hours of admission. The MMSE includes 23 items (total score 0 30) that screen for cognitive impairment. A score of 23 or less is defined as possible cognitive
 impairment.<sup>31</sup>

271 *Delirium.* The Confusion Assessment Method (CAM), the short 4 item version, is used to assess the

presence and duration of delirium.<sup>37</sup> The CAM is widely used by physician and nurse practitioners to

diagnose delirium (sensitivity of 53-90% and specificity of 84-100%).<sup>38</sup> It consists of four items: 1)

presence of acute onset and fluctuation 2) inattention 3) disorganized thinking and 4) altered level of

275 consciousness.<sup>37</sup> The CAM is filled out within 24 hours of admission. Moreover, the risk on

276 developing delirium is assessed using the Dutch VMS criteria for risk on delirium.<sup>39</sup> Nurse

practitioners will score the CAM daily from day 1 till day 8 of admission, if there are signs of possible

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2 3 4	278	delirium at day 8, these measurements are continued until discharge. In addition, during the first
5 6	279	three days of admission the Delirium Observation Screening Scale (DOSS) is scored during each
7 8	280	nursing shift and is continued when there is a clinical suspicion of delirium. <sup>40</sup>
9 10 11 12	281	3. Psychosocial functioning and quality of life
13 14	282	Apathy. We use three items of the Geriatric Depression Scale (GDS-15) to assess apathy (sensitivity of
15 16 17	283	69% and specificity of 85%). These items include the following questions: 1) 'Do you prefer to stay at
18 19	284	home, rather than going out and doing new things' 2) 'Have you dropped many of your activities and
20 21 22	285	interests?' And 3) 'Do you feel full of energy'. A score of >2 points is classified as 'apathy present'. <sup>41</sup>
23 24	286	Social network and informal care. Participants are asked if they receive informal care, how many
25 26	287	hours a week, what type of care (housekeeping and/or personal care) and from which persons
27 28 29	288	(partners, children, other family members or neighbours/volunteers).
30 31 32	289	Health-Related Quality of Life. This will be measured by determining Health-Related Quality of Life
33 34	290	using the EuroQoL-5D (EQ-5D). The EQ-5D is a broadly used and validated instrument for measuring
35 36	291	generic health-related quality of life. <sup>34</sup> It consists of 5 dimensions: 1) mobility 2) self-care 3) usual
37 38	292	activities 4) pain/discomfort 5) anxiety/depression. We will use the EQ-5D-3L which has three
39 40 41	293	options: no problems, some problems or severe problems. In addition, the following questions will
41 42 43	294	be used to assess self-reported quality of life: 1) How would you rate your quality of life in general ?
44 45	295	(excellent, very good, good, moderate, bad) 2) How would you rate your quality of life in general at
46 47	296	this time compared to 6 months ago? (much better, somewhat better, more or less the same,
48 49	297	somewhat worse, much worse) 3) How would you grade your life at this moment, with a range
50 51 52	298	between 0 and a 100? <sup>42</sup>
53 54	200	
55 56	299	4. Physical functioning
57 58		
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*Risk of functional decline.* Patients are assessed for risk of functional decline using the Identification
of Seniors at Risk- Hospitalized patients (ISAR-HP), scores of two and up indicate at an increased risk
for functional decline.<sup>43</sup> *Functioning level.* The 15-item modified KATZ score is used to measure Activities of Daily Living (ADL)functioning. This included assessment of performance in basic ADL- KATZ-6), as in instrumental ADL
(KATZ-9).<sup>44,45</sup> We measure KATZ-score both currently (at admission), as two weeks before admission,

306 reflecting pre-morbid level of functioning. (I)ADL-functional is also included in follow-up

307 measurements.

308 (Im)mobility. We will assess mobility by reviewing three questions that are in the admission
 309 assessment regarding: 1) use of a walking aid (from KATZ-15), and from the CGA: 2) being able to
 310 walk outside of the house for five minutes (two weeks before and currently) and 3) performing, and
 311 frequency of, physical activity.<sup>46</sup>

312 Handgrip strength. Physiotherapists measure muscle weakness in all admitted patients using
 313 maximum handgrip strength (JAMAR). 47

7 314 *Gait speed.* Gait speed is measured as part of the Short Physical Performance Battery (SPBB) that is

<sup>9</sup> 315 part of the physiotherapist' admission assessment.<sup>48</sup>

316 Falls. Fall history is assessed by asking the number of falls in the past six months, if yes, how many
 317 times did you fall?<sup>39</sup> During the discharge assessment the occurrence of falls in the AGCH and the

318 consequences of falls (indication for prolonged stay, diagnostics or injury) are recorded.

6 319 *Fear of falling.* We will use a Numeric Rating Scale (NRS, score 0-10) to assess fear of falling, 0

2 320 indicates no fear of falling, and 10 the greatest fear of falling possible.<sup>49</sup>

5 321 Pain. Widely used in clinical practice the standard for pain assessment is the Numeric Rating Scale,

322 ranging from 0 to 10, in which a score of 0 represents no pain and 10 represents the worst possible

60 323 pain.<sup>50</sup>

2 3	224	Fatigue A Numeric Dating Scale from 0.10 is used 0 indicating no fatigue and 10 indicating the
4 5 6 7	324	<i>Fatigue.</i> A Numeric Rating Scale from 0-10 is used, 0 indicating no fatigue and 10 indicating the
	325	greatest fatigue ever felt by the participant. <sup>51</sup>
8 9 10	326	Sleep. Participants are asked if there have been difficulties with sleeping in the past month and
10 11 12 13 14 15 16 17	327	whether participants have used sleep medication.
	328	Nutrition. We will use the Short Nutritional Assessment Questionnaire (SNAQ) for identifying
	329	malnourished patients. The SNAQ consists of three questions on weight loss, appetite and drink/tube
18 19 20	330	nutrition, resulting in a score ranging from 0 to 5. 0 and 1 are defined as 'no malnutrition' 2 as
21 22	331	'moderate malnutrition' and 3 or more as 'severe malnutrition'. <sup>52</sup>
23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38 30 41 42 43 44 50 51 23 54 55	332	5. Healthcare utilization and satisfaction with care
	333	Medical care during admission and process of discharge. The following are collected from patient
	334	electronic health records: the diagnostics performed in the AGCH, revisits to the hospital, admission
	335	to the hospital, length of stay of the AGCH, discharge destination and time needed to send medical
	336	handovers to the general practitioner.
	337	Hospital readmission. This outcome will be assessed during follow-up. Follow-up will consist of three
	338	telephone interviews at 1, 3 and 6 months after discharge. Readmission will be both assessed by
	339	interview as by checking care data from an aggregated database of expense claims of various
	340	healthcare insurers. Data that will be collected are: number of readmissions, total days of
	341	readmission, reasons for readmission and whether the readmission was planned or unplanned.
	342	Emergency department (ED) visits. ED visits will be assessed during follow-up and checked in
	343	insurance data, we will record the number of separate ED visits.
	344	Outpatient hospital visits. We will ask patients if there have been any outpatient visits in the past
56 57 58 59 60	345	month(s), and if so how many.

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346 Consultations by general practitioner. We will ask patients if there have been any consultations by 347 the general practitioner (both during the day as during out-of-office hours) visits in the past 348 month(s), and if so how many.

349 Consultations by physiotherapist or dietician. We will ask patients if there have been any

350 consultations by a physiotherapist of dietician in the past month(s), and if so how many.

351 Home care. This includes questions on frequency of home care, including housekeeping, personal

352 care and nursing care. We will also include days of day care and hours of informal care provided by family members or friends.

354 Temporary admission to a nursing home. Days of (temporary) admission to a skilled nursing facility or rehabilitation facility. 355

356 Permanent Institutionalization. This concerns long-term admission to a skilled nursing facility and 357 date of admission to this facility.

358 Patient satisfaction with care. Patients or informal caregivers are asked to fill out an 8-question 359 questionnaire regarding their satisfaction with the care that they received. Questions are answered 360 on a 5- level Likert scale.<sup>53</sup>

Sample Size calculation 362

363 The dataset of the transitional care bridge includes data of 674 patients of conventionally

hospitalized; approximately 26% experienced a readmission at 90 days.<sup>32</sup> Assuming that 19% of 364

365 patients admitted to the AGCH will experience a 90 day readmission, data from 523 patients of AGCH

366 will give us 80% power to detect an absolute difference of 7% in readmission rate (which is a 27%

367 reduction in relative risk) using a two-sided Fisher's Exact Test with an alpha of 0.05. As we expect

368 10% loss to follow-up, we will aim to include a total of 576 (= 523\*1.1) patients from the AGCH.

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3 4 5	369	Planned statistical analysis
6 7	370	The participant flow diagram according to the STROBE guidelines will show a summary of admissions
8 9	371	and study recruitment at the AGCH and will provide study discontinuation rates at 1, 3 and 6 months
10 11	372	follow-up. <sup>30</sup> We will describe demographic, clinical and prognostic characteristics of the study
12 13 14	373	participants at baseline. The number of participants with missing data will be collected and described
14 15 16	374	alongside our variables to check for the pattern of missingness. Inversely-weighted propensity scores
17 18	375	will be used to control for any imbalances between the treatment groups. <sup>54</sup> Propensity scores will be
19 20	376	calculated using generalized booted methods. Balance and overlap of propensity scores distribution
21 22 23	377	will be assessed. Propensity score weights for the estimation of the average treatment effect will be
23 24 25	378	created using all covariates where groups differed on baseline or that were associated with 90-day
26 27	379	readmission rate. As this is a repeated measures design, we will assume equal weighting for all
28 29	380	measurements. <sup>55</sup>
30 31 32	381	All hypotheses will be tested using two-tailed- significance level of 0.05. Descriptive analyses will be
33 34	382	performed to examine participant's characteristics. Differences in changes over time in outcomes will
35 36 37	383	be compared between groups using multilevel models. All models will include a main effect of
38 39	384	treatment group, a linear term for time and an interaction between time and treatment group.
40 41	385	Models will be checked with residual and appropriate goodness-of-fit statistics.
42 43	386	
44 45 46	387	Economic evaluation
47 48	388	A healthcare and societal perspective is planned for this economic evaluation. <sup>56</sup> The evaluation from
49 50 51	389	the healthcare perspective will only include direct medical costs accrued in the six months after the
52 53	390	admission to the AGCH. Propensity scores will also be used in the economic evaluation. Missing data
54 55	391	will be imputed using multiple imputation chained equations if necessary, for cost and effect data.
56 57	392	We plan to use generalized linear regression models with a gamma distribution and an identity link
58 59 60	393	to account for the right skew of cost data. A generalized linear regression model will be used to
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estimate the incremental effect in quality adjusted life years (QALYs) adjusted for baseline utility
estimates with a Gaussian distribution and identify link.<sup>57</sup> Incremental cost-effectiveness ratios will
be calculated using the pooled cost and effect estimates. Bootstrapped cost-effect pairs will be
plotted on a cost-effectiveness plane and used to estimate cost-effectiveness acceptability curves.<sup>58</sup>

## *Process evaluation; adherence, barriers and facilitators to implementation.*

We plan to use a qualitative study design to describe barriers and facilitators to implementation of the AGCH. This will include semi-structured interviews with various stakeholders, emergency department staff, geriatricians, nurses, physiotherapists, discharge nurses, home care, hospital administrators, and insurance companies. We will assess barriers and facilitators to implementation at different levels: micro (healthcare professionals), meso (care organizations) and macro level (legal and financial framework). Interviews will be typed verbatim and analysed by two researchers independently, using thematic analysis.<sup>59</sup> The findings will be summarized in matrices with facilitators and barriers at different levels (micro, meso, macro) to develop a guideline for implementation of the AGCH elsewhere.<sup>60</sup>

#### 409 Discussion

The complex acute medical needs of older patients require the delivery of specialized geriatric care, however the traditional hospital environment may not support recovery and maintaining independence. The AGCH aims to deliver care that focusses both on medical treatment, early rehabilitation and proper transitions of care for older adults with multiple chronic conditions.<sup>29,61</sup> The AGCH is unique in the Netherlands in its aim to combine multiple evidenced-based components of care for frail older persons in an alternative location for hospital care. The proposed research will provide insight into the clinical and economic effectiveness of care delivered at the AGCH, compared to hospital care. Limitations to the design are that it is non-randomized study and that historic cohorts are used as control groups. Strengths are that patients and informal caregivers were

3 4	419	involved in the design of the concept of the AGCH. Moreover, a process evaluation will address the
5 6	420	barriers and facilitators to implementation of a community hospital such as the AGCH in the existing
7 8 9	421	health care system of the Netherlands. This research will provide valuable insights into the
9 10 11 12	422	implementation of this concept of care in other regions of the Netherlands and abroad.
13 14 15	423	Ethics and Dissemination
16 17 18	424	This trial will be carried out in accordance with the declaration of Helsinki and current ethical
19 20	425	requirements. The Medical Ethics Research Committee (METC) confirmed that the Medical Research
21 22	426	Involving Human Subjects Act did not apply to this research project and official approval was not
23 24 25	427	required. The outcomes of this trial will be reported according to STROBE guidelines for cohort
25 26 27	428	studies. <sup>30</sup> This study will evaluate both the effectiveness of this type of care delivery as of the costs
28 29	429	that are involved, allowing for implementation elsewhere. The findings of this study will be published
30 31	430	in peer-reviewed journals.
32 33	431	
34 35	432	Acknowledgements
36	433	The authors thank all (care) professionals from the Amsterdam University Medical Centres, Cordaan
37	434	and Zilveren Kruis who have worked on the development of the AGCH. Thank you for your time
38	435	advise and cooperation.
39 40	436	
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		Author contributions
42	437	Author contributions MER. JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and
43	437 438	MER, JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and
43 44	437 438 439	MER, JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and BMB made substantial contributions to the design and clinical aspects of the of the protocol. BMB
43 44 45	437 438 439 440	MER, JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and BMB made substantial contributions to the design and clinical aspects of the of the protocol. BMB conceived the study and wrote funding applications. All authors critically revised the manuscript and
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2 3	453	Comr	peting interests statement- None Declared
4	455 454		s approval – The Medical Ethics Research Committee (METC) of the Amsterdam University
5	454		cal Centres, location Amsterdam Medical Centre (AMC) confirmed that the Medical Research
6 7	456		ving Human Subjects Act did not apply to this research project and official approval was not
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## Box 1 - Components of Acute Geriatric Care (AGCH) Hospital intervention and goals

1) Patients receive a full CGA work-up and interdisciplinary assessment, including physiotherapy treatment plan.

2) There is special attention paid to discharge and follow-up planning; if needed, patients are seen

post-discharge at the outpatient clinic or through a community nurse. Community nurses receive

warm-handovers from AGCH staff.<sup>62</sup>

3) 50% of discharge letters are sent to the general practitioner within 24 hours after the patient is

discharged.<sup>63,64</sup>

**Table 1** Overview of the content and description of (outcome) measurements and timing of measurements at the Acute Community Care Hospital ('WijkKliniek')

	Description and/or instrument	H1	H2	P1	P3	P6
1. Medical and demogra	aphical data		1			
Sociodemographic data	Date of birth, age at admission, sex, level of education, living conditions, marital state	R				
Data on admission	Time spent at the ED, admission diagnosis, date and time of admission	R				
Chronic conditions	Charlson Comorbidity index <sup>36</sup>	R				
Polypharmacy	Number of drugs <sup>65</sup>	R				
Mortality	Date of death		R	R	R	R
2. Cognitive functioning						
Cognitive impairment	Mini Mental State Exam (MMSE) <sup>31</sup>	R				
Delirium	Safety management system patient screening (VMS) <sup>39</sup> Confusion Assessment Method (CAM) <sup>37</sup> Delirium Observation Scale (DOS) <sup>40</sup>	N/ D	N/ D			
3. Psychosocial function			1			
Apathy	Geriatric Depression Scale (GDS-3) <sup>41</sup>	Ν	R	R	R	R
Social network and informal care	Presence and frequency of informal care	R		R	R	R
Quality of life and health status	EQ-5D-3L <sup>34</sup>	R		R	R	R
4. Physical functioning	6.					
Identifying at-risk- patients	ISAR-HP- Identifying Seniors at Risk score <sup>43</sup>	N				
Functional status	Activities of daily Living (ADL) modified Katz-ADL score <sup>33</sup>	N				
(Im)mobility	Using walking aid, information in KATZ-15 questions on exercise	N				
Handgrip strength	Jamar <sup>47</sup>	Р				
Gait speed	Short Physical Performance Battery SPPB <sup>48</sup>	Р				
Falling	Fall history Falls in the AGCH	N	R	R	R	R
	Numeric Rating scale (NRS) fear of falling <sup>49</sup>	N	R	R	R	R
Pain	Numeric Rating Scale (NRS) pain <sup>50</sup>	N	R	R	R	R
Fatigue	Numeric Rating Scale (NRS) fatigue <sup>51</sup>	Ν	R	R	R	R
Nutrition	Short Nutritional Assessment Questionnaire (SNAQ- Score) <sup>52</sup>	N				
5. Healthcare utilizatior	and satisfaction with care					
Medical care during admission	Diagnostics performed in the AGCH Readmission to university hospital Length of stay at the AGCH		R			
Hospital readmission	Readmission rate to the hospital or AGCH		R	R	R	R

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temporary institutional care, primary			
care.			
Satisfaction with Care 8 question questionnaire <sup>53</sup>	R	(R)	

H1= at admission, H2= at discharge, P1= one month after discharge, P3 = three months after discharge, P6 = six months after discharge. N=nurse Geriatric Community Care Hospital P= physiotherapist D= Doctor/attending physician R= researcher/research nurse

STROBE Statement—Checklist of items that should be i	included in reports of <i>cohort studies</i>
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	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) Give the eligibility criteria, and the sources and methods of selection of
1		participants. Describe methods of follow-up
		(b) For matched studies, give matching criteria and number of exposed and unexposed
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effec
		modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) If applicable, explain how loss to follow-up was addressed
		( <u>e</u> ) Describe any sensitivity analyses
Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially
		eligible, examined for eligibility, confirmed eligible, included in the study,
		completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and
		information on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Report numbers of outcome events or summary measures over time
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and
		their precision (eg, 95% confidence interval). Make clear which confounders were
		adjusted for and why they were included
		(b) Report category boundaries when continuous variables were categorized
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a
		meaningful time period

Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other information		
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

\*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

## **BMJ Open**

# An acute geriatric community hospital for older adults: a study protocol for a prospective controlled observational study.

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3 4	1	An acute geriatric community hospital for older adults: a study protocol for a prospective
5	2	controlled observational study.
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4 5	35	<b>Keywords:</b> geriatric medicine, older adults, community hospital, intermediate care facilities,
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### 55 Abstract

1 2 3

Introduction: Hospital admission is associated with unwanted outcomes like readmission,
institutionalization, functional decline, and mortality in older adults with multiple chronic conditions.
Providing acute care in the community and integrating effective components of care models might
lead to a reduction of negative outcomes. Recently, the first geriatrician-led care Acute Geriatric
Community Hospital (AGCH) was introduced in the Netherlands. Care at the AGCH is focused on:
treatment of acute disease, comprehensive geriatric assessment, setting patient-led goals, early
rehabilitation and stream-lined transitions of care.

63 Methods and analysis: This prospective cohort study will investigate the effectiveness of care 64 delivery at the AGCH on patient outcomes, by comparing AGCH patients to two historic cohorts of 65 hospitalized patients. Propensity score matching will correct for potential population differences. The primary outcome is the three-month unplanned readmission rate. Secondary outcomes include: 66 functional decline, institutionalization, healthcare utilization, occurrence of delirium or a fall, health-67 68 related quality of life, mortality and patient satisfaction. Measurements will be conducted at 69 admission, discharge and one, three and six months after discharge. Furthermore, an economic 70 evaluation and qualitative process evaluation to assess facilitators and barriers for implementation is 71 planned.

*Ethics and dissemination:* The study will be conducted according to the Declaration of Helsinki. The
Medical Ethics Research Committee (METC) confirmed that the Medical Research Involving Human
Subjects Act did not apply to this research project and official approval was not required. The
findings of this study will be disseminated through academic and public lectures, scientific
conferences and in peer-reviewed journals. Furthermore, the findings of this study will aid in the
implementation and financing of this concept (inter)nationally. *Trial Registration Number* NL7896; pre-results

2 3	81	Strengths and limitations of this study:
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6	82	- This study will be the first to evaluate an acute geriatric community hospital in the Netherlands
7 8	83	on both patient reported and economic outcomes.
9	84	- Patients, informal caregivers and professionals were involved in the design, and implementation
10 11	85	of the Acute Geriatric Community Hospital.
12 13	86	- A process evaluation is planned to describe the experience of various stakeholders with this new
14	87	concept and reveal barriers and facilitators to its' implementation.
15 16	88	- A limitation of this study is the use of two historic cohorts as control population, as this may
17	89	result in baseline differences between the control and intervention population
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31 32	96	result in baseline differences between the control and intervention population
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2 3 4	110	Introduction
5 6 7	111	Background
8 9	112	Throughout the western world, there is an increase of older adults requiring acute care. Inpatient
10 11	113	services are mostly consumed by those over the age of 65. <sup>1,2</sup> The Netherlands, like many other
12 13 14	114	countries, recently (2015) implemented stay-at-home policies leading to an increase of frail older
15 16	115	persons living longer in the community. <sup>3</sup> These reforms juxtaposed with an increased aging
17 18	116	population, contribute to increased acute care utilization. <sup>4</sup> There has been a 19% increase in
19 20 21	117	emergency department visits by Dutch older adults based on data from 2015 versus 2017. <sup>5,6</sup>
22 23	118	Many older adults come to the hospital with complex and atypical health problems. <sup>5,7</sup> When older
24 25 26	119	persons are subsequently hospitalized, health outcomes are known to be poor, <sup>8</sup> particularly in
27 28	120	patients with geriatric syndromes such as cognitive impairment or mobility impairment. <sup>9,10</sup> For
29 30	121	example, previous research showed that 30% of older persons gained new disabilities and 20% were
31 32	122	readmitted within 30 days postdischarge. <sup>11,12</sup> Hospitalization itself may contribute to these poor
33 34 35	123	outcomes as hospitalized older adults often have reduced mobility while bedbound for
36 37	124	approximately 20 hours daily. <sup>13,14</sup> Low physical activity, in combination with poor nourishment and
38 39	125	increased caloric demand due to acute illness can lead to loss of muscle mass and may contribute to
40 41	126	the development of new disabilities, particularly in frail patients. <sup>15,16</sup> Together with noise in a hospital
42 43 44	127	environment and different personnel rotating through patient rooms, this contributes to sensory
45 46	128	overstimulation and sleep deprivation, which may lead to confusion and the occurrence of
47 48	129	delirium. <sup>17,18,19</sup> Not only is the patient affected during hospitalization, informal caregivers also find
49 50	130	hospital admissions stressful. <sup>20</sup> Furthermore, previous research shows that lack of discharge planning
51 52 53	131	in the hospital can result in the care needs of patients being unmet. <sup>21</sup> Hospital care as usual
54 55	132	compared to discharge planning and follow-up showed an increase in early readmissions. <sup>22</sup>
56 57 58 59 60	133	Readmissions can further effect patients' recovery and increase healthcare costs. <sup>23</sup>

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The complex medical needs of older persons, combined with their more dependent social situation

requires care delivery that offers guidance and support of realistic health and life goals.<sup>24</sup> Perhaps a

'gap' exists between what care can be provided in an acute care hospital, that is secondary care, with

a focus on medical treatment and diagnostics, versus what can be provided in the community, that is

Several alternative strategies to hospital admission and (nurse-led) intermediate care have been

intermediate care and subacute geriatric care units, low-tech but with geriatric expertise.<sup>26,27</sup> In

to care as usual.<sup>25,26</sup> Until recently, the Netherlands however, had limited alternatives to

developed in the past as a substitute to conventional hospitalization.<sup>25</sup> Examples include (nurse-led)

general, these types of care have comparable outcomes to hospital care as usual. Moreover, nurse-

led care in the US, observation units and hospital at home care all showed a cost reduction compared

hospitalization for older persons who required acute care. Therefore, our research group sought to

create an acute care alternative and opened the Acute Geriatric Community Care Hospital (AGCH) in

company (Zilveren Kruis) and a home care and nursing home agency (Cordaan). This acute geriatric

care unit, which is based within an intermediate care facility, provides an alternative to conventional

The AGCH delivers acute care that is focused on early mobilization and rehabilitation. Older persons

with common medical problems (such as urinary tract infections, pneumonia or heart failure) and

form of intermediate care between primary and secondary care. In the Netherlands, primary care

includes general practice, community nursing and (temporary) admission to nursing home.

Secondary care includes medical specialist care and hospital admission. Care is supervised by a

or community nurse. The single rooms are designed to accommodate respite for the informal

geriatrician and provided by nurses trained in geriatric care who have experience as either a hospital

geriatric syndromes requiring hospital admission can be admitted to the AGCH. The AGCH provides a

July 2018, partnering with an academic hospital (Amsterdam UMC, location AMC), an insurance

primary care focused on rehabilitation, nursing care and wellbeing.

hospitalization and delivers acute care closer to home.

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3 4	159	caregivers. This concept of care is new to the Netherlands, to our knowledge there is only one
5 6	160	example in Europe to which it compares: a "subacute care unit" in intermediate care, which has been
7 8 9	161	implemented in Spain. <sup>27</sup>
9 10 11	162	Our hypothesis is that with the provision of integrated medical and nursing care close to home, the
12 13	163	AGCH is better suited to the needs of older adults with multiple chronic conditions and will lead to
14 15	164	better patient health outcomes and reduced post-acute care costs. Therefore, this study is designed
16 17 19	165	to compare care provided for older patients in the AGCH versus care provided in a hospital setting.
18 19 20	166	Specifically we aim to:
21 22 23	167	> Evaluate the 90-day readmission rate of patients acutely admitted to AGCH compared to a
24 25	168	traditional hospital (usual care). Secondary outcomes include: functional decline,
26 27	169	institutionalization, healthcare utilization, the occurrence of geriatric syndromes such as
28 29	170	delirium, health-related quality of life, mortality, and patient satisfaction;
30 31 32	171	Assess the cost-effectiveness of the AGCH versus usual care by performing an economic
33 34	172	evaluation from a health care provider and societal perspective;
35 36	173	Conduct a process evaluation using interviews with key stakeholders to identify facilitators
37 38	174	and barriers to the implementation of the AGCH.
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42 43 44	176	<u>Methods</u>
45 46	177	Setting
47 48 49	178	The Acute Geriatric Community Hospital opened in July 2018. It serves both the south-eastern part of
50 51	179	Amsterdam and its surrounding areas (an area with approximately 147 500 inhabitants). <sup>28</sup> The AGCH
52 53	180	is a 23 -bed facility within an skilled nursing facility. The hospital has 24-hour geriatric and nursing
54 55 56	181	assistance, physiotherapy and routine laboratory testing during the workweek and simple x-ray
57 58	182	available once a week. The population that is eligible for admission to the AGCH includes patients
59 60	183	with 1) acute medical problems requiring hospitalization (e.g. pneumonia, exacerbation of heart

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184 failure or an urinary tract infection) 2) geriatric conditions (e.g. delirium, cognitive impairment, falls, 185 functional impairment), who are 3) hemodynamically stable and 4) not in need of complex diagnostic 186 testing. In general, patients will not be admitted if they: 1) require care that can only be provided at 187 an intensive care unit 2) require surgery 3) require urgent treatments or diagnostic tests that can 188 only be provided in-hospital (e.g. endoscopy, interventional radiology) 4) do not need hospital care, 189 but require transfer to a skilled nursing facility and 5) live in another region of the Netherlands. 190 Patients are directly admitted to the AGCH from the emergency department (ED) of the Amsterdam 191 UMC- location Academic Medical Centre (AMC) in Amsterdam which is a 1000-bed academic hospital 192 with approximately 30,000 ED visits yearly. After the on-call geriatrician has assessed that patient is 193 eligible for AGCH admission and the patient or representative has agreed to admission, the patient is 194 transferred to the AGCH by ambulance. Since October 2019 patients can also be transferred from 195 EDs of other hospitals in Amsterdam. In the future we plan to admit patients from home or a General 196 Practice office. Patients are admitted between 8.00 am and 11.00 pm, 7 days a week. At admission, a 197 Comprehensive Geriatric Assessment (CGA) is conducted.<sup>29</sup> The CGA gives an overview of all medical, 198 functional, psychological and social problems that are discussed during multidisciplinary team 199 meetings and are used to formulate a care plan for each patient. For an overview of the admission 200 process, admission criteria and components of this intervention see figure 1.

202 Study design

This study is a prospective, observational, cohort study with two historical control groups to evaluate
the clinical and economic effects of the AGCH. The STROBE statement was used in preparing the
study protocol.<sup>30</sup> (Appendix 1) Participants will be compared to hospital controls. The participants
are recruited into the study and are assessed at admission, discharge, one month, three and six
months after discharge. The recruitment phase of this study started in February 2019. We plan to
recruit for 18 to 24 months. The first three months of data collection will consist of a piloting phase
to assess the feasibility of data-collection and follow-up. In addition, a qualitative process evaluation

Patients admitted to the AGCH are eligible for inclusion to the study. However, patients are excluded

from the study if: 1) the attending physician judges that the patient is too ill to participate e.g. is

legal representative does not speak or understand Dutch or English. In the case of cognitively

participation and acts as healthcare-proxy. Cognitive functioning is assessed by the attending

physician and confirmed by the researcher by conducting a Mini Mental State Exam (MMSE). A

MMSE score of 15 or less Indicates severe cognitive impairment, in which the approval of a legal

Two completed studies conducted by our research group were selected as historical control groups.

These control groups were selected based on characteristics of the participants -primary admission

diagnosis, department, area of residence- and the availability and reproductively of the data. The

recruited between September 2010 and March 2014 originating from the greater Amsterdam area in

the Netherlands.<sup>32</sup> Participants were patients of 65 years and older admitted for at least 48 hours to

first control group from the Transitional Care Bridge Study consists of 674 patients that were

an internal medicine ward. Proxy consent was provided for participants suffering from severe

cognitive impairment (Mini Mental State Exam<sup>31</sup> (MMSE)  $\leq$ 15). They participated in a negative

randomized controlled trial that assessed the effectiveness of a nurse-led transitional care program

in preventing functional decline.<sup>32</sup> The second control group (Hospital-ADL study<sup>10</sup>) consists of 401

impaired or delirious patients, patients can only be included if a legal representative consents to

terminally ill 2) the patient or legal representative does not consent to participate. 3) the patient or

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*Participants* 

representative will be sought.<sup>31</sup>

Historical control groups

on facilitators and barriers to the implementation of the AGCH and patient experience will beconducted.

1		
2 3 4 5 6 7 8 9 10 11	235	patients that were recruited between October 2015 and June 2017, also originating from the greater
	236	Amsterdam area. These participants were enrolled in a prospective cohort studying the trajectory of
	237	functional decline in older hospitalized adults. Participants were aged 70 years and older,
	238	hospitalized for at least 48 hours. Patients suffering from severe cognitive impairment (MMSE ≤15)
12 13	239	and delirium were excluded from participation. For the detailed methodology and inclusion criteria
14 15	240	of the two control cohorts we refer to the study protocols and papers of these studies. <sup>10,32-34</sup>
16 17	241	
18 19 20	242	Patient and public involvement
21 22	243	Older persons living in Amsterdam were involved in the design of the AGCH concept. There was no
23 24	244	patient involvement in the design of this study.
25 26 27	245	
28 29 30 31 32 33 34 35 36 37 38	246	Outcomes
	247	The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.
	248	Secondary outcomes measured at 1,3 and 6 months will include:
	249	1) ADL-functioning as defined by the KATZ-ADL scale. <sup>35</sup>
	250	2) Healthcare utilization, including institutionalization in a long-term care facility.
39 40 41	251	3) Occurrence of delirium and/or falls.
42 43	252	4) Health-related quality of life (HRQoL). <sup>36</sup>
44 45	253	5) All-cause mortality.
46 47 48 49 50	254	6) Satisfaction of patients and primary care givers with the care provided.
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51 52	256	Data collection
53 54 55	257	Eligible patients and/or legal representatives will be contacted and informed about the study
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58 59	258	procedures after which written informed consent is obtained. Inclusion and interviewing of patients
60	259	is conducted by an onsite researcher. Routine data on functioning and risk assessments are collected
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by a trained registered nurse and physiotherapist as part of the CGA for each patient.<sup>37</sup> Table 1 gives 260 261 an overview of measurement of primary and secondary outcomes over time. These measurements 262 were chosen based on the assessments and data collected from the two historic control groups. 263 Measurements during admission are at H1 which is within 48 hours after admission and H2 which is 264 within 48 hours before discharge. Follow-up is completed by telephone at 1,3 and 6 months after 265 discharge (P1, P3 and P6). 266 Data collection includes: 267 1. Medical and demographical data 268 Sociodemographic data. These will include age, gender, highest level of education, ethnicity, marital 269 status and living arrangement. 270 Time spent at the ED, admission diagnosis, date and time of admission. 271 Chronic conditions. The number and severity of chronic conditions will be assessed using the Charlson 272 Comorbidity Index.<sup>38</sup> This index is commonly used to indicate the risk of mortality; each condition is 273 scored 1, 2, 3 or 6 points, with a higher total number of points indicating a greater risk at death. 274 Polypharmacy. Polypharmacy will be assessed by counting the number of individual drugs that are 275 chronically prescribed to a participant, in which a number of 5 or more drugs is considered 276 polypharmacy. 277 Mortality. This will be assessed during follow-up, where possible by reviewing patients electronic 278 files, otherwise from general practice registries. 279 2. Cognitive functioning.

Cognitive impairment. This will be is assessed by reviewing the score of the Mini Mental State Exam

(MMSE) that is performed within 48 hours of admission. The MMSE includes 23 items (total score 0-

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282 30) that screen for cognitive impairment. A score of 23 or less is defined as possible cognitive
283 impairment.<sup>31</sup> When a patient is delirious upon inclusion the MMSE is not conducted.

284 Delirium. The Confusion Assessment Method (CAM), the short 4 item version, is used to assess the 285 presence and duration of delirium.<sup>39</sup> The CAM is widely used by physician and nurse practitioners to 286 diagnose delirium (sensitivity of 53-90% and specificity of 84-100%).<sup>40</sup> The CAM is filled out within 24 hours of admission. Moreover, the risk on developing delirium is assessed using the Dutch VMS 287 288 criteria for risk on delirium.<sup>41</sup> Nurse practitioners will score the CAM daily from day one till day three 289 of admission, if there are signs of possible delirium at day 3, these measurements are continued until 290 the symptoms are resolved. In addition, during the first three days of admission the Delirium 291 Observation Screening Scale (DOSS) is scored during each nursing shift and is continued when there 292 is a clinical suspicion of delirium.<sup>42</sup>

## 293 3. Psychosocial functioning and quality of life

Apathy. We use three items of the Geriatric Depression Scale (GDS-15) to assess apathy (sensitivity of
 69% and specificity of 85 %). These items include the following questions: 1) 'Do you prefer to stay at
 home, rather than going out and doing new things' 2) 'Have you dropped many of your activities and
 interests?' And 3) 'Do you feel full of energy'. A score of >2 points is classified as 'apathy present'. <sup>43</sup>

Social network and informal care. Participants are asked if they receive informal care, how many
hours a week, what type of care (housekeeping and/or personal care) and from which persons
(partners, children, other family members or neighbours/volunteers).

Health-Related Quality of Life. This will be measured by determining Health-Related Quality of Life
 using the EuroQoL-5D (EQ-5D). The EQ-5D is a broadly used and validated instrument for measuring
 generic health-related quality of life.<sup>36</sup>

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## 305 4. Physical functioning

306 *Risk of functional decline.* Patients are assessed for risk of functional decline using the Identification
307 of Seniors at Risk- Hospitalized patients (ISAR-HP), scores of two and up indicate at an increased risk
308 for functional decline.<sup>44</sup>

309 Functioning level. The 15-item modified KATZ score is used to measure Activities of Daily Living (ADL)-

310 functioning. This included assessment of performance in basic ADL- KATZ-6), as in instrumental ADL

311 (KATZ-9).<sup>45,46</sup> We measure KATZ-score both currently (at admission), as two weeks before admission,

312 reflecting pre-morbid level of functioning. (I)ADL-functional is also included in follow-up

3 313 measurements.

(*Im*)*mobility*. We will assess mobility by reviewing three questions that are in the admission

315 assessment regarding: 1) use of a walking aid (from KATZ-15), and from the CGA: 2) being able to

316 walk outside of the house for five minutes (two weeks before and currently) and 3) performing, and

317 frequency of, physical activity.<sup>47</sup>

318 Handgrip strength. Physiotherapists measure muscle weakness in all admitted patients using
 7
 8 319 maximum handgrip strength (JAMAR). 48

0 320 *Gait speed.* Gait speed is measured as part of the Short Physical Performance Battery (SPBB) that is

321 part of the physiotherapist' admission assessment.<sup>49</sup>

322 *Falls.* Fall history is assessed by asking the number of falls in the past six months<sup>41</sup> During the

323 discharge assessment the occurrence of falls in the AGCH and the consequences of falls (indication

324 for prolonged stay, diagnostics or injury) are recorded.

3 325 *Fear of falling.* We will use a Numeric Rating Scale (NRS, score 0-10) to assess fear of falling, 0

<sup>5</sup> 326 indicates no fear of falling, and 10 the greatest fear of falling possible.<sup>34</sup>

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2 3	327	<i>Pain.</i> Widely used in clinical practice the standard for pain assessment is the Numeric Rating Scale,
4 5 6 7	328	ranging from 0 to 10, in which a score of 0 represents no pain and 10 represents the worst possible
8 9	329	pain. <sup>50</sup>
10 11 12	330	Fatigue. A Numeric Rating Scale from 0-10 is used, 0 indicating no fatigue and 10 indicating the
13 14	331	greatest fatigue ever felt by the participant. <sup>51</sup>
15 16 17	332	<i>Sleep.</i> Participants are asked if they have had difficulties with sleeping in the past month and
18 19 20	333	whether participants have used sleep medication.
21 22	334	Nutrition. We will use the Short Nutritional Assessment Questionnaire (SNAQ) for identifying
23 24	335	malnourished patients. The SNAQ consists of three questions on weight loss, appetite and drink/tube
25 26 27	336	nutrition, resulting in a score ranging from 0 to 5. 0 and 1 are defined as 'no malnutrition' 2 as
28 29	337	'moderate malnutrition' and 3 or more as 'severe malnutrition'. <sup>52</sup>
30 31 32 33	338	5. Healthcare utilization and satisfaction with care
33 34 35	339	Medical care during admission and process of discharge. The following are collected from patient
36 37	340	electronic health records: the diagnostics performed in the AGCH, revisits to the hospital, admission
38 39	341	to the hospital, length of stay of the AGCH, discharge destination and time needed to send medical
40 41 42	342	handovers to the general practitioner.
43 44 45	343	Hospital readmission. This outcome will be assessed during follow-up. Follow-up will consist of three
46 47	344	telephone interviews at 1, 3 and 6 months after discharge. Readmission will be both assessed by
48 49	345	interview as by checking care data from an aggregated database of expense claims of various
50 51 52	346	healthcare insurers. Data that will be collected are: number of readmissions, total days of
53 54	347	readmission, reasons for readmission and whether the readmission was planned or unplanned.
55 56 57	348	Emergency department (ED) visits. ED visits will be assessed during follow-up and checked in
58 59 60	349	insurance data. We will record the number of separate ED visits.

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350	Outpatient hospital visits. We will ask patients if there have been any outpatient visits in the past
351	month(s), and if so how many.
352	Consultations by general practitioner. We will ask patients if there have been any consultations by
353	the general practitioner (both during the day as during out-of-office hours) visits in the past
354	month(s), and if so how many.
355	Consultations by physiotherapist or dietician. We will ask patients if there have been any
356	consultations by a physiotherapist of dietician in the past month(s), and if so how many.
357	Home care. This includes questions on frequency of home care, including housekeeping, personal
358	care and nursing care. We will also include days of day care and hours of informal care provided by
359	family members or friends.
360	Temporary admission to a nursing home. Days of (temporary) admission to a skilled nursing facility or
361	rehabilitation facility.
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362	Permanent Institutionalization. This concerns long-term admission to a skilled nursing facility and
363	date of admission to this facility.
364	Patient satisfaction with care. Patients or informal caregivers are asked to fill out an 8-question
365	questionnaire regarding their satisfaction with the care that they received. Questions are answered
366	on a 5- level Likert scale. <sup>53</sup>
367	Sample Size calculation
368	In the Hospital-ADL study 34 % of participants experienced a readmission at 90 days. <sup>34</sup> Assuming that
369	26% of patients admitted to the AGCH will experience a 90 day readmission, data from 515 patients
370	of AGCH will yield 80% power to detect an absolute difference of 8% in readmission rate (which is a
371	25% reduction in relative risk) using a two-sided test with an alpha of 0.05. <sup>54</sup> As we expect 10% loss
372	to follow-up, we will aim to include a total of 567 (= 515*1.10) patients from the AGCH.

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3 4	373	Planned statistical analysis
5 6 7	374	The complete participant flow diagram will show a summary of admissions and study recruitment at
, 8 9	375	the AGCH and will provide study discontinuation rates at 1, 3 and 6 months follow-up. <sup>30</sup> We will
10 11	376	describe demographic, clinical and prognostic characteristics of the study participants at baseline.
12 13	377	The number of participants with missing data will be collected and described alongside our variables
14 15 16	378	to check for the pattern of missingness. Inversely-weighted propensity scores will be used to control
17 18	379	for any imbalances between the treatment groups. <sup>55</sup> Propensity scores will be calculated using
19 20	380	generalized booted methods. Balance and overlap of propensity scores distribution will be assessed.
21 22	381	Propensity score weights for the estimation of the average treatment effect will be created using all
23 24 25	382	covariates where groups differed on baseline or that were associated with 90-day readmission rate.
26 27 28	383	As this is a repeated measures design, we will assume equal weighting for all measurements. <sup>56</sup>
28 29 30	384	All hypotheses will be tested using two-tailed- significance level of 0.05. All secondary outcomes will
31 32	385	be adjusted for multiple testing using a Hochberg method. <sup>57,58</sup> Descriptive analyses will be performed
33 34 25	386	to examine participant's characteristics. Differences in changes over time in outcomes will be
35 36 37	387	compared between groups using multilevel models. All models will include a main effect of
38 39	388	treatment group, a linear term for time and an interaction between time and treatment group.
40 41	389	Models will be checked with residual and appropriate goodness-of-fit statistics.
42 43	390	
44 45 46	391	Economic evaluation
47 48	392	A healthcare and societal perspective is planned for this economic evaluation. The evaluation from
49 50 51	393	the healthcare perspective will only include direct medical costs accrued in the six months after the
52 53	394	admission to the AGCH. Direct medical cost will only include costs that are funded through the Dutch
54 55	395	healthcare system. The evaluation from a societal perspective will include an estimation of the cost
56 57	396	of informal care. Costs will be based on the reference prices found in the Dutch Manual for Costing
58 59 60	397	studies and will be set for final year of data collection (2020 or 2021). According to this guideline

costs will be discounted at 4% and quality adjusted life years (QALYs) will be discounted at 1,5 %. <sup>59</sup> Propensity scores will also be used in the economic evaluation. Missing data will be imputed using multiple imputation chained equations if necessary, for cost and effect data. We plan to use generalized linear regression models with a gamma distribution and an identity link to account for the right skew of cost data. A generalized linear regression model will be used to estimate the incremental effect in QALYs. adjusted for baseline utility estimates with a Gaussian distribution and identify link.<sup>60</sup> Incremental cost-effectiveness ratios will be calculated using the pooled cost and effect estimates. Bootstrapped cost-effect pairs will be plotted on a cost-effectiveness plane and used to estimate cost-effectiveness acceptability curves.<sup>61</sup>

#### Process evaluation and patient experience

We plan to use a qualitative study design to describe barriers and facilitators to implementation of the AGCH- concept and describe experiences of patients and healthcare professionals with the AGCH. We will conduct semi-structured interviews with various stakeholders, such as geriatricians, nurses, physiotherapists and hospital administrators. These interviews will concern the implementation of the AGCH concept. In addition, semi-structured interviews with patients and informal caregivers will be conducted in order to describe the patient experience and satisfaction with this new form of care. A representative sample of patients and/or caregivers who participate in the prospective cohort study will approached and invited to be interviewed shortly after the discharge from the AGCH. Stakeholders and healthcare professionals will be selected by a researcher and will be invited for an interview to discuss their experience and opinion on the AGCH. Interviews will be typed verbatim and analysed by two researchers independently, using thematic analysis.<sup>62</sup> In our analysis of barriers and facilitators to implementation, we will describe these factors at different levels: micro (healthcare professionals), meso (care organizations) and macro level (legal and financial framework).<sup>63</sup> The findings will be summarized in matrices with facilitators and barriers at different

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3 4	423	levels (micro, meso, macro) and can be used to develop a guideline for implementation of the AGCH
5 6 7	424	elsewhere. <sup>64</sup>
8 9 10	425	
11 12 13 14	426	Preliminary results
15 16 17	427	Between February 1 <sup>st</sup> and December 20 <sup>th</sup> 2019 there were 362 consecutive admissions to the AGCH.
18 19	428	Of these admissions 26 were readmissions of patients who were already study participants. Of the
20 21	429	remaining 336 admissions 90 were by patients who did not meet the inclusion criteria. Of the
22 23	430	remaining patients 246 patients or legal representatives and healthcare-proxy were approached for
24 25 26	431	participation; 212 consented to participation. (figure 2) The healthcare – proxy provided informed
26 27 28	432	consent in 62 (29.2 %) of cases. 16 patients did not consent to follow-up by telephone but did
29 30	433	consent to medical record review. The total study sample as of December 20 <sup>th</sup> 2019 consisted of 212
31 32	434	participants at baseline. Table 2 displays the baseline characteristics of this group. Participants had a
33 34	435	mean age (standard deviation) of 81.8 (8.4) years, 47.6 % were male. Most participants were living
35 36 37	436	independently before admission (81.1%). Most frequent admission diagnosis were infectious
38 39	437	diseases (28.3%, mostly urinary tract infections), respiratory-related (25.5%, including pneumonia
40 41	438	which was over half respiratory-related and exacerbations of COPD), and other (geriatric) diagnoses
42 43	439	such as falls, delirium or sudden unexplained functional decline (30.2%). Cardiac (9.4%) admission
44 45 46	440	diagnosis concerned mostly exacerbations of heart failure. Median length of stay was (interquartile
40 47 48	441	range) 8.0 days (5.0-12.0) and 83.7 % were discharged to their original living situation.
49 50 51	442	
52 53 54 55	443	Discussion
56 57 58	444	The complex acute medical needs of older patients require the delivery of specialized geriatric care.
59 60	445	The traditional hospital environment may however not support recovery and maintaining

independence. The AGCH aims to deliver care that focusses both on medical treatment, early
rehabilitation and proper transitions of care for older adults with multiple chronic conditions.<sup>29,65</sup> The
AGCH is unique in the Netherlands in its aim to combine multiple evidenced-based components of
care for frail older persons at an alternative location for hospital care. The proposed research will
provide insight into the clinical and economic effectiveness of care delivered at the AGCH, compared
to hospital care.

Our preliminary results show that data collection at the AGCH is feasible and we expect to recruit enough patients to evaluate the primary outcome. There are also limitations to the design of this study. It is a non-randomized study and that historic cohorts are used as control groups. Therefore baseline differences between intervention and control groups may hamper the matching between the groups. Also, as the data from the cohorts were not collected in the same time period as the AGCH cohort there may be external non-observed differences in the Dutch healthcare system and work processes in hospitals may have changed over the years. However, the two control populations were not self-selected and do represent a geriatric population suffering from common exacerbations of chronic conditions and acute illness that occur in older persons. Strengths are that patients and informal caregivers were involved in the design of the concept of the AGCH. Moreover, a process evaluation will address the barriers and facilitators to implementation of a community hospital such as the AGCH in the existing health care system of the Netherlands. This research will provide valuable insights into the implementation of this concept of care in other regions of the Netherlands and abroad.

) 466

# 467 <u>Ethics and Dissemination</u>

468 This study will be carried out in accordance with the declaration of Helsinki and current ethical
469 requirements. The outcomes of this study will be reported according to STROBE guidelines for cohort

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3 4	470	studies. <sup>30</sup> This study will evaluate both the effectiveness of this type of care delivery as of the costs
5 6	471	that are involved, allowing for implementation elsewhere. The findings of this study will be published
7 8 9	472	in peer-reviewed journals.
10	473	
11	474	Acknowledgements
12 13	475	The authors thank all (care) professionals from the Amsterdam University Medical Centres, Cordaan
13 14	476	and Zilveren Kruis who have worked on the development of the AGCH. Thank you for your time,
15	477	advise and cooperation. Also, we would like to thank the members of the AGCH-study group, these
16	478	are the clinicians who work at the Geriatrics Department of the Amsterdam University Medical
17 18	479	Centres and who support the data-collection at the AGCH.
18 19	480	
20	481	Author contributions
21	482	MER, JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and
22 23	483	BMB made substantial contributions to the design and clinical aspects of the of the protocol. BMB
25 24	484	conceived the study and wrote funding applications. All authors critically revised the manuscript and
25	485	approved the final version of this manuscript.
26	486	approved the final version of this manuscript.
27 28	487	Funding statement
28 29	488	This research received funding though ZonMw, the Netherlands Organization for Health Research
30		
31	489	and Development, project number 808393598041. The care provided at the AGCH (WijkKliniek) is
32 33	490	provided in a partnership between Cordaan, a community and home-care organization and the
33 34	491	Amsterdam University Medical Centres, location Academic Medical Centre. The AGCH (WijkKliniek) is
35	492	financially supported by Zilveren Kruis, a health insurance company.
36	493	
37	494	Patient consent
38 39	495	Not required.
40	496	
41	497	Competing interests statement- None Declared
42	498	
43 44	499	Ethics approval
45	500	Based on the study protocol, the Ethics Committee (METC) of the Amsterdam University Medical
46	501	Center waived the obligation for the study to undergo formal ethical approval as is described under
47	502	Dutch law in the Medical Research in Humans Act, January 2019. (ref W17_474 # 19.001) As this is a
48 49	503	prospective study and pseudonymized data is used written informed consent was obtained from the
50	504	participants prior participation. This is in line with current European legislation under the General
51	505	Data Protection Regulation (GDPR).
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# Figure 1 – Patient admission process and criteria, components of AGCH intervention and goals

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CGA= Comprehensive Geriatric Assessment<sup>29</sup> **GP=** General Practitioner

net<sup>29</sup>

Figure 2 Diagram	of patient par	ticipation betw	een February 1 <sup>st</sup>	and December 2	20 <sup>th</sup> 2019.
	or putient put	cicipation betw			2015.

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**Table 1** Overview of the content and description of (outcome) measurements and timing ofmeasurements at the Acute Community Care Hospital ('WijkKliniek')

	Description and/or instrument	H1	H2	P1	P3	Pe
1. Medical and demogra						
Sociodemographic data	Date of birth, age at admission, sex, level of education, living conditions, marital state	R				
Data on admission	Time spent at the ED, admission diagnosis, date and time of admission	R				
Chronic conditions	Charlson Comorbidity index <sup>38</sup>	R				
Polypharmacy	Number of drugs	R				
Mortality	Date of death		R	R	R	R
2. Cognitive functioning						
Cognitive impairment	Mini Mental State Exam (MMSE) <sup>31</sup>	R				
Delirium	Safety management system patient screening (VMS) <sup>41</sup> Confusion Assessment Method (CAM) <sup>39</sup> Delirium Observation Scale (DOS) <sup>42</sup>	N/ D	N/ D			
3. Psychosocial function						
Apathy	Geriatric Depression Scale (GDS-3) <sup>43</sup>	Ν	R	R	R	R
Social network and informal care	Presence and frequency of informal care	R		R	R	R
Quality of life and health status	EQ-5D-3L <sup>36</sup>	R		R	R	R
4. Physical functioning	6.					
Identifying at-risk- patients	ISAR-HP- Identifying Seniors at Risk score <sup>44</sup>	N				
Functional status	Activities of daily Living (ADL) modified Katz-ADL score <sup>35</sup>	N				
(Im)mobility	Using walking aid, information in KATZ-15 questions on exercise	N				
Handgrip strength	Jamar <sup>48</sup>	Р				
Gait speed	Short Physical Performance Battery SPPB <sup>49</sup>	Р				
Falling	Fall history Falls in the AGCH	N	R	R	R	R
	Numeric Rating scale (NRS) fear of falling <sup>34</sup>	N	R	R	R	R
Pain	Numeric Rating Scale (NRS) pain <sup>50</sup>	Ν	R	R	R	R
Fatigue	Numeric Rating Scale (NRS) fatigue <sup>51</sup>	Ν	R	R	R	R
Nutrition	Short Nutritional Assessment Questionnaire (SNAQ- Score) <sup>52</sup>	N				
5. Healthcare utilization	and satisfaction with care					
Medical care during admission	Diagnostics performed in the AGCH Readmission to university hospital Length of stay at the AGCH		R			
Hospital readmission	Readmission rate to the hospital or AGCH		R	R	R	R

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Health care utilization	Home care, medical specialist care, temporary institutional care, primary	R		R	R	R
	care.					
Satisfaction with Care	8 question questionnaire <sup>53</sup>		R	(R) *		

H1= at admission, H2= at discharge, P1= one month after discharge, P3 = three months after discharge, P6 = six months after discharge. N=nurse Geriatric Community Care Hospital P= physiotherapist D= Doctor/attending physician R= researcher/research nurse \*in case to per teries only assessment was missed at H2

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## Table 2 Baseline characteristics of study participants

Variable	N=212
Age in years, mean (SD)	81.8 (8.4)
Male, N(%)	101 (47.6)
Living arrangements before admission, N (%)	
Independent	172 (81.1)
Assisted living/ senior residence	31 (14.6)
Nursing home/other	9 (4.2)
Marital status, N (%)	
Widow/widower	94 (44.5)
Married or living together	71 (33.6)
Single or divorced	46 (21.8)
Education, N(%)	
Primary school	36 (18.7)
Elementary technical/domestic science school	41 (21.2)
Secondary vocational education	65 (33.7)
Higher level high school/third-level education	51 (26.4)
Born in the Netherlands, N (%)	158 (76.0)
ADL-score upon admission (KATZ-6 <sup>a</sup> ), median (IQR)	3.0 (1.0-5.0
MMSE score <sup>b</sup> , mean (SD)	23.7 (4.7)
Polypharmacy <sup>c</sup> , N(%)	159 (75.0)
Hospitalization in past 6 months, N (%)	61 (31.1)
Charlson Comorbidity Index <sup>d</sup> (mean, SD)	2.8 (2.0)
Primary admission diagnosis, N (%)	
Infectious diseases	60 (28.3)
Respiratory (including pneumonia)	54 (25.5)
Gastrointestinal	9 (4.2)
Cardiac	20 (9.4)
Neurology	16 (7.5)
Other (e.g. falls, delirium, sudden unexplained functional	53 (30.2)
decline)	

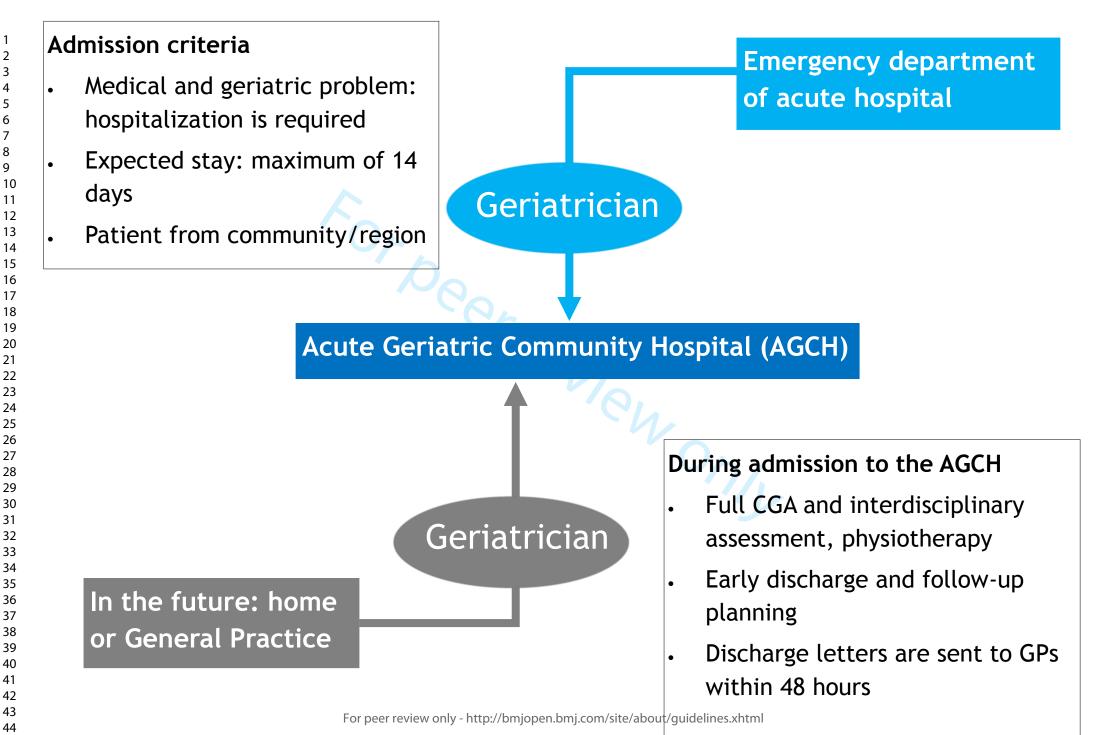
SD, standard deviation; IQR, interquartile range

<sup>a</sup>Score ranging from 0-6, with a higher score indicating more dependence in activities of daily living<sup>35</sup>
 <sup>b</sup>Score ranging from 0-30, with a score of ≤23 indicating possible cognitive impairment <sup>31</sup>

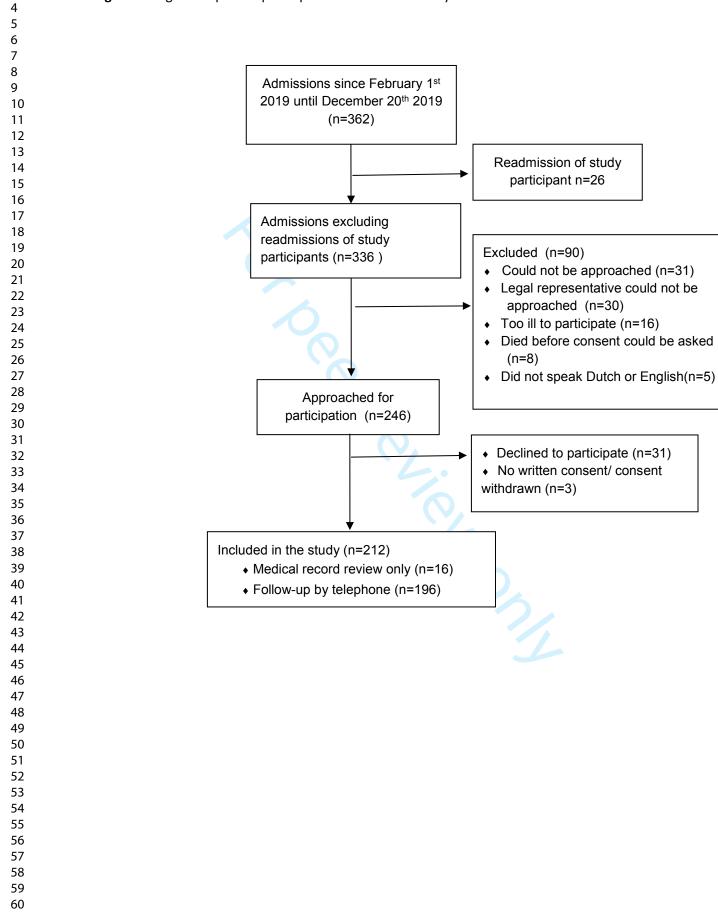
<sup>c</sup>Use of 5 drugs or more

<sup>d</sup>Range of 0-31, with a higher score indicating more severe comorbidity<sup>38</sup>

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# **Figure 2** Diagram of patient participation between February 1<sup>st</sup> and December 20<sup>th</sup> 2019.



# Appendix 1 STROBE statement checklist

STROBE Statement—Checklist of items that should be included in reports of cohort studies

	ltem No	Recommendation	Item found on page
Title and abstract	1	(a) Indicate the study's design with a commonly used term in	1 and 3
		the title or the abstract	
		(b) Provide in the abstract an informative and balanced	Page 3
		summary of what was done and what was found	
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5-7
Objectives	3	State specific objectives, including any prespecified	Page 7
		hypotheses	
Methods			
Study design	4	Present key elements of study design early in the paper	Page 8 -9
Setting	5	Describe the setting, locations, and relevant dates, including	Page 7-15
		periods of recruitment, exposure, follow-up, and data	
		collection	
Participants	6	(a) Give the eligibility criteria, and the sources and methods	Page 7-10
		of selection of participants. Describe methods of follow-up	and 11
		(b) For matched studies, give matching criteria and number	Page 9
		of exposed and unexposed	and 10
Variables	7	Clearly define all outcomes, exposures, predictors, potential	Page 11 –
		confounders, and effect modifiers. Give diagnostic criteria, if	15
		applicable	
Data sources/	8*	For each variable of interest, give sources of data and details	Page 11-
measurement		of methods of assessment (measurement). Describe	15
		comparability of assessment methods if there is more than	
		one group	
Bias	9	Describe any efforts to address potential sources of bias	Page 16
Study size	10	Explain how the study size was arrived at	Page 15
Quantitative variables	11	Explain how quantitative variables were handled in the	Page 16
		analyses. If applicable, describe which groupings were	
		chosen and why	
Statistical methods	12	(a) Describe all statistical methods, including those used to	Page 16
		control for confounding	

		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	Page 16
		(d) If applicable, explain how loss to follow-up was addressed	Page 16
		( <u>e</u> ) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow- up, and analysed	Page 18 and 26 (figure 3
		(b) Give reasons for non-participation at each stage	Page 18 and 26 (figure
		(c) Consider use of a flow diagram	Page 26 figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 18 and 29
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	n/a
Main results	16	( <i>a</i> ) Give unadjusted estimates and, if applicable, confounder- adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(b) Report category boundaries when continuous variables were categorized	Page 29
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a
Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 19

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Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 19
Generalisability	21	Discuss the generalisability (external validity) of the study results	n/a
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 20

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.

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# Investigating the effectiveness of care delivery at an acute geriatric community hospital for older adults in the Netherlands: a protocol for a prospective controlled observational study

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3 4	1	Investigating the effectiveness of care delivery at an acute geriatric community hospital for older
5	2	adults in the Netherlands: a protocol for a prospective controlled observational study
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8 9	4	Marthe E. Ribbink MD <sup>1</sup> , Janet L. MacNeil Vroomen PhD <sup>1,2</sup> , Rosanne van Seben PhD <sup>1</sup> , Irène Oudejans
10	5	MD, PhD <sup>1</sup> , Bianca M. Buurman RN, PhD <sup>1,3</sup> on behalf of the AGCH study group.
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28 29 30 31 32 33 34 35	16	Abstract: 264
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36 37	20	Supplementary material: STROBE checklist and 1 supplementary table
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3	35	Keywords: geriatric medicine, older adults, community hospital, intermediate care facilities,
4 5	36	readmissions, functional decline.
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### 55 Abstract

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Introduction: Hospital admission in older adults with multiple chronic conditions is associated with
unwanted outcomes like readmission, institutionalization, functional decline, and mortality.
Providing acute care in the community and integrating effective components of care models might
lead to a reduction in negative outcomes. Recently, the first geriatrician-led Acute Geriatric
Community Hospital (AGCH) was introduced in the Netherlands. Care at the AGCH is focused on the
treatment of acute diseases, comprehensive geriatric assessment, setting patient-led goals, early
rehabilitation and streamlined transitions of care.

Methods and analysis: This prospective cohort study will investigate the effectiveness of care 63 64 delivery at the AGCH on patient outcomes by comparing AGCH patients to two historic cohorts of 65 hospitalized patients. Propensity score matching will correct for potential population differences. The primary outcome is the three-month unplanned readmission rate. Secondary outcomes include 66 functional decline, institutionalization, healthcare utilization, occurrence of delirium or falls, health-67 68 related quality of life, mortality and patient satisfaction. Measurements will be conducted at 69 admission, discharge and one, three and six months after discharge. Furthermore, an economic 70 evaluation and qualitative process evaluation to assess facilitators and barriers to implementation 71 are planned.

*Ethics and dissemination:* The study will be conducted according to the Declaration of Helsinki. The Medical Ethics Research Committee (METC) confirmed that the Medical Research Involving Human Subjects Act did not apply to this research project and official approval was not required. The findings of this study will be disseminated through public lectures, scientific conferences and journal publications. Furthermore, the findings of this study will aid in the implementation and financing of this concept (inter)nationally.

78 Trial Registration Number NL7896; pre-results

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2 3 4	81	Strengths and limitations of this study:
5 6	82	- This study will be the first to evaluate an acute geriatric community hospital in the Netherlands
7	83	on both patient-reported and economic outcomes.
8 9	84	- Patients, informal caregivers and professionals were involved in the design and implementation
10 11	85	of the Acute Geriatric Community Hospital (AGCH).
12	86	- A process evaluation is planned to describe the experience of various stakeholders with this new
13 14	87	concept and reveal barriers and facilitators to its implementation.
15 16	88	- A limitation of this study is the use of two historic cohorts as the control population, which may
17	89	result in baseline differences between the control and intervention population.
18 19 20	90	result in baseline differences between the control and intervention population.
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3 4	110	Introduction
5 6 7	111	Background
8 9	112	Throughout the western world, there is an increase in older adults requiring acute care. Inpatient
10 11	113	services are mostly consumed by those over the age of 65. <sup>1,2</sup> The Netherlands, like many other
12 13 14	114	countries, recently (2015) implemented stay-at-home policies leading to an increase in frail older
15 16	115	persons living longer in the community. <sup>3</sup> These reforms juxtaposed with an increased ageing
17 18	116	population contribute to increased acute care utilization. <sup>4</sup> There has been a 19% increase in
19 20 21	117	emergency department (ED) visits by Dutch older adults based on data from 2015 versus 2017. <sup>5,6</sup>
22 23	118	Many older adults come to the hospital with complex and atypical health problems. <sup>5,7</sup> When older
24 25 26	119	persons are subsequently hospitalized, health outcomes are known to be poor, <sup>8</sup> particularly in
26 27 28	120	patients with geriatric syndromes such as cognitive impairment or mobility impairment. <sup>9,10</sup> For
29 30	121	example, previous research showed that 30% of older persons gained new disabilities and 20% were
31 32	122	readmitted within 30 days postdischarge. <sup>11,12</sup> Hospitalization itself may contribute to these poor
33 34	123	outcomes, as hospitalized older adults often have reduced mobility because they are bedbound for
35 36 37	124	approximately 20 hours a day. <sup>13,14</sup> Low physical activity, in combination with poor nourishment and
38 39	125	increased caloric demand due to acute illness, can lead to the loss of muscle mass and may
40 41	126	contribute to the development of new disabilities, particularly in frail patients. <sup>15,16</sup> Together with the
42 43	127	noise in a hospital environment and the different personnel rotating between patient rooms, this
44 45 46	128	contributes to sensory overstimulation and sleep deprivation, which may lead to confusion and the
47 48	129	occurrence of delirium. <sup>17,18,19</sup> Not only is the patient affected during hospitalization but the informal
49 50	130	caregivers also find hospital admissions stressful. <sup>20</sup> Furthermore, previous research shows that a lack
51 52	131	of discharge planning in the hospital can result in patients' care needs being unmet. <sup>21</sup> Hospital care
53 54 55	132	as usual compared to discharge planning and follow-up show a higher rate of early readmissions. <sup>22</sup>
55 56 57 58 59 60	133	Readmissions can further affect patients' recovery and increase healthcare costs. <sup>23</sup>

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The complex medical needs of older persons, combined with their more dependent social situation,
requires care delivery that offers guidance and support for realistic health and life goals.<sup>24</sup> Perhaps a
'gap' exists between what care can be provided in an acute care hospital versus what can be
provided in the community (primary care). Acute hospital care is secondary care with a focus on
medical treatment and diagnostics, whilst primary care focuses on rehabilitation, nursing care and
wellbeing.

140 Several alternative strategies to hospital admission and (nurse-led) intermediate care have been developed in the past as a substitute to conventional hospitalization.<sup>25</sup> Examples include (nurse-led) 141 142 intermediate care and subacute geriatric care units, which are low-tech but with geriatric 143 expertise.<sup>26,27</sup> In general, these types of care have comparable outcomes to hospital care as usual. 144 Moreover, nurse-led care in the United States, observation units and hospital at home care all show a cost reduction compared to care as usual.<sup>25,26</sup> Until recently, the Netherlands had limited alternatives 145 146 to hospitalization for older persons who required acute care. Therefore, our research group sought 147 to create an acute care alternative and opened the Acute Geriatric Community Care Hospital (AGCH) 148 in July 2018, partnering with an academic hospital (Amsterdam UMC, location AMC), an insurance 149 company (Zilveren Kruis) and a home care and nursing home agency (Cordaan). This acute geriatric 150 care unit, which is based within an intermediate care facility, provides an alternative to conventional 151 hospitalization and delivers acute care closer to home.

The AGCH delivers acute care that is focused on early mobilization and rehabilitation. Older persons
with common medical problems (such as urinary tract infections, pneumonia or heart failure) and
geriatric syndromes requiring hospital admission can be admitted to the AGCH. The AGCH provides a
form of *intermediate* care between primary and secondary care. In the Netherlands, primary care
includes general practice, community nursing and (temporary) admission to a nursing home.
Secondary care includes specialist medical care and hospital admission. The care at the AGCH is
supervised by a geriatrician and provided by nurses trained in geriatric care who have experience as

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3 4	159	either a hospital or community nurse. The single rooms are designed to accommodate respite for the
5 6	160	informal caregivers. This concept of care is new to the Netherlands, and to our knowledge, there is
7 8	161	only one comparable example in Europe: a "subacute care unit" in intermediate care, which has been
9 10 11	162	implemented in Spain. <sup>27</sup>
11 12 13	163	Our hypothesis is that with the provision of integrated medical and nursing care close to home, the
14 15	164	AGCH is better suited to the needs of older adults with multiple chronic conditions and will lead to
16 17	165	better patient health outcomes and reduced post-acute care costs. Therefore, this study is designed
18 19 20	166	to compare care provided for older patients in the AGCH versus care provided in a hospital setting.
20 21 22	167	Specifically, we aim to:
23		
24 25	168	Evaluate the 90-day readmission rate of patients acutely admitted to the AGCH compared to
26 27	169	a traditional hospital (usual care). Secondary outcomes include functional decline,
28 29 30	170	institutionalization, healthcare utilization, the occurrence of geriatric syndromes such as
31 32	171	delirium, health-related quality of life, mortality, and patient satisfaction;
33 34	172	Assess the cost-effectiveness of the AGCH versus usual care by performing an economic
35 36	173	evaluation from a health care provider and societal perspective;
37 38	174	Conduct a process evaluation using interviews with key stakeholders to identify facilitators
39 40	175	and barriers to the implementation of the AGCH.
41 42 43	176	and barriers to the implementation of the AGCH.
44		
45 46	177	Methods
47 48 49	178	Setting
50 51	179	The AGCH opened in July 2018. It serves the south-eastern part of Amsterdam and its surrounding
52 53	180	areas (an area with approximately 147 500 inhabitants). <sup>28</sup> The AGCH is a 23-bed facility within a
54 55 56	181	skilled nursing facility. The hospital has 24-hour geriatric and nursing assistance. Physiotherapy and
50 57 58	182	routine laboratory testing are available during the workweek and simple X-ray is available once a
59 60	183	week. The population that is eligible for admission to the AGCH are patients with a combination of an

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3 4	184	acute medical problem requiring hospitalization (e.g., pneumonia, exacerbation of heart failure or a
5 6	185	urinary tract infection), and a geriatric condition (e.g., delirium, cognitive impairment, falls, or
7 8	186	functional impairment). Additionally, patients have to be haemodynamically stable and should not
9 10 11	187	require complex diagnostic testing. In general, patients will not be admitted if they have the
12 13	188	following exclusion criteria: 1) require care that can only be provided at an intensive care unit, 2)
14 15	189	require surgery, 3) require urgent treatments or diagnostic tests that can only be provided in-hospital
16 17 19	190	(e.g., endoscopy, interventional radiology), 4) do not need hospital care but require transfer to a
18 19 20	191	skilled nursing facility and 5) live in another region of the Netherlands.
21 22	192	Patients are directly admitted to the AGCH from the ED of the Amsterdam UMC-location Academic
23 24	193	Medical Centre (AMC) in Amsterdam, which is a 1000-bed academic hospital with approximately 30
25 26 27	194	000 ED visits yearly. After the on-call geriatrician has assessed whether the patient is eligible for
27 28 29	195	AGCH admission and the patient or representative has agreed to admission, the patient is transferred
30 31	196	to the AGCH by ambulance. Since October 2019, patients can also be transferred from the EDs of
32 33	197	other hospitals in Amsterdam. In the future, we plan to admit patients from home or general practice
34 35	198	offices. Patients are admitted between 8.00 am and 11.00 pm, seven days a week. At admission, a
36 37 38	199	Comprehensive Geriatric Assessment (CGA) is conducted. <sup>29</sup> The CGA gives an overview of all medical,
39 40	200	functional, psychological and social problems. The CGA is discussed during multidisciplinary team
41 42	201	meetings and used to formulate a care plan for each patient. For an overview of the admission
43 44	202	process, the admission criteria and the components of this intervention, see figure 1.
45 46 47	203	
48	204	Study design

This study is a prospective, observational, cohort study with two historical control groups to evaluate the clinical and economic effects of the AGCH. The STROBE statement was used in preparing the study protocol (appendix 1).<sup>30</sup> Participants will be compared to hospital controls. The participants are recruited into the study and are assessed at admission, discharge, and one, three and six months after discharge. Recruitment for this study started in February 2019. We plan to recruit for 18 to 24 

months. The first three months of data collection consisted of a piloting phase to assess the feasibility of data collection and follow-up. In addition, a qualitative process evaluation on the facilitators and barriers to the implementation of the AGCH and patient experience will be conducted.

#### *Participants*

Patients admitted to the AGCH are eligible for inclusion in the study. However, patients are excluded from the study if: 1) the attending physician judges that the patient is too ill to participate, e.g., the patient is terminally ill, 2) the patient or legal representative does not consent to participate, or 3) the patient or legal representative does not speak or understand Dutch or English. In the case of cognitively impaired or delirious patients, patients can only be included if a legal representative consents to participation and acts as healthcare proxy. Cognitive functioning is assessed by the attending physician and confirmed by the researcher by conducting a Mini-Mental State Examination (MMSE).<sup>31</sup> An MMSE score of 15 or less indicates severe cognitive impairment, in which the approval of a legal representative will be sought.

#### Historical control groups

We selected two completed cohort studies that were conducted by our research group as historical control groups. We expect that the patients from these cohorts have similar admission diagnoses as those who can be admitted to the AGCH, namely, diagnoses that are ambulatory care sensitive conditions such as infections and exacerbations of COPD or heart failure. Patients in these two cohorts were admitted to internal medicine, cardiology, pulmonology and geriatrics departments. These departments admit patients with diagnoses similar to those that can be admitted to the AGCH. In addition, we have selected these cohorts as control groups as the patients come from the same area as the studied population admitted to the AGCH, that is, the greater Amsterdam area. The first 

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235	control group from the Transitional Care Bridge Study consists of 674 patients who were recruited
236	between September 2010 and March 2014. <sup>32</sup> Participants were patients of 65 years and older
237	hospitalized for at least 48 hours. Proxy consent was provided for participants suffering from severe
238	cognitive impairment (MMSE $\leq$ 15). They participated in a negative randomized controlled trial that
239	assessed the effectiveness of a nurse-led transitional care programme in preventing functional
240	decline. <sup>32</sup> The second control group from Hospital-ADL study consists of 401 patients who were
241	recruited between October 2015 and June 2017. <sup>10</sup> These participants were enrolled in a prospective
242	cohort studying the trajectory of functional decline in older hospitalized adults. Participants were
243	aged 70 years and older and were hospitalized for at least 48 hours. Patients suffering from severe
244	cognitive impairment (MMSE $\leq$ 15) and delirium were excluded from participation. For the detailed
245	methodology and inclusion criteria of the two control cohorts, please refer to the study protocols
246	and papers of these studies. <sup>10,32-34</sup>
247	
248	Patient and public involvement
249	Older persons living in Amsterdam were involved in the design of the AGCH concept. No patients
249 250	Older persons living in Amsterdam were involved in the design of the AGCH concept. No patients were involved in the design of this study.
250	
250 251	were involved in the design of this study.
250 251 252	were involved in the design of this study. Outcomes
250 251 252 253	were involved in the design of this study. <i>Outcomes</i> The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.
250 251 252 253 254	were involved in the design of this study. <i>Outcomes</i> The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital. Secondary outcomes measured at one, three and six months will include:
250 251 252 253 254 255	<ul> <li>were involved in the design of this study.</li> <li><i>Outcomes</i></li> <li>The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.</li> <li>Secondary outcomes measured at one, three and six months will include:</li> <li>1) Activities of daily living (ADL)-functioning, as defined by the Katz-ADL scale.<sup>35</sup></li> </ul>
250 251 252 253 254 255 256	<ul> <li>were involved in the design of this study.</li> <li><i>Outcomes</i></li> <li>The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.</li> <li>Secondary outcomes measured at one, three and six months will include:</li> <li>1) Activities of daily living (ADL)-functioning, as defined by the Katz-ADL scale.<sup>35</sup></li> <li>2) Healthcare utilization, including institutionalization in a long-term care facility.</li> </ul>
250 251 252 253 254 255 256 257	<ul> <li>were involved in the design of this study.</li> <li><i>Outcomes</i></li> <li>The primary outcome measure is the 3-month unplanned readmission rate to the AGCH or hospital.</li> <li>Secondary outcomes measured at one, three and six months will include: <ol> <li>Activities of daily living (ADL)-functioning, as defined by the Katz-ADL scale.<sup>35</sup></li> <li>Healthcare utilization, including institutionalization in a long-term care facility.</li> </ol> </li> <li>Occurrence of delirium and/or falls.</li> </ul>

# 261 Data collection

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6 7 8	262	Eligible patients and/or legal representatives will be contacted and informed about the study
9 10	263	procedures after which written informed consent is obtained. Inclusion and interviewing of patients
11 12	264	is conducted by an onsite researcher. Routine data on functioning and risk assessments are collected
13 14	265	by a trained registered nurse and physiotherapist as part of the CGA for each patient. <sup>37</sup> Table 1 gives
15 16 17	266	an overview of measurement of the primary and secondary outcomes over time. These
18 19	267	measurements were chosen based on the assessments and data collected from the two historic
20 21	268	control groups. The supplementary table provides an overview of the content and timing of
22 23 24	269	measurements in the AGCH-group compared to the two historic control groups. Measurements
24 25 26	270	during admission are at H1, which is within 48 hours after admission, and H2, which is within 48
27 28	271	hours before discharge. Follow-up is completed by telephone at one, three and six months after
29 30	272	discharge (P1, P3 and P6).
31 32 33 34	273	Data collection includes:
35 36 37	274	1. Medical and demographical data
38 39	275	Sociodemographic data. These will include age, gender, highest level of education, ethnicity, marital
40 41 42	276	status and living arrangement.
43 44 45	277	Time spent at the ED, admission diagnosis, and date and time of admission.
46 47 48	278	Chronic conditions. The number and severity of chronic conditions will be assessed using the Charlson
49 50	279	Comorbidity Index. <sup>38</sup> This index is commonly used to indicate the risk of mortality; each condition is
51 52 53	280	scored 1, 2, 3 or 6 points, with a higher total number of points indicating a greater risk of death.
54 55	281	Polypharmacy. Polypharmacy will be assessed by counting the number of individual drugs that are
56 57 58	282	chronically prescribed to a participant, in which a number of 5 or more drugs is considered
58 59 60	283	polypharmacy.

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2 3 4	284	Mortality. This will be assessed during follow-up, either from the patients' electronic files or from
5 6 7	285	general practice registries.
8 9	286	2. Cognitive functioning.
10 11 12	287	Cognitive impairment. This is assessed by reviewing the score of the MMSE that is performed within
13 14 15	288	48 hours of admission. The MMSE includes 23 items (total score 0-30) that screen for cognitive
15 16 17	289	impairment. A score of 23 or less is defined as possible cognitive impairment. <sup>31</sup> When a patient is
18 19	290	delirious upon inclusion, the MMSE is not conducted.
20 21 22	291	Delirium. The Confusion Assessment Method (CAM), 4 item short version, is used to assess the
23 24	292	presence and duration of delirium. <sup>39</sup> The CAM is widely used by physicians and nurse practitioners to
25 26 27	293	diagnose delirium (sensitivity of 53-90% and specificity of 84-100%). <sup>40</sup> The CAM is filled out within 24
27 28 29	294	hours of admission. Moreover, the risk on developing delirium is assessed using the Dutch Safety
30 31	295	Management Programme (Veiligheidsmanagementsysteem (VMS)) criteria for risk of delirium. <sup>41</sup>
32 33	296	Nurse practitioners will score the CAM daily from day one till day three of admission; if there are
34 35	297	signs of possible delirium at day 3, these measurements are continued until the symptoms are
36 37 38	298	resolved. In addition, during the first three days of admission, the Delirium Observation Screening
39 40	299	Scale (DOSS) is scored during each nursing shift and is continued when there is a clinical suspicion of
41 42 43	300	delirium. <sup>42</sup>
44 45 46	301	3. Psychosocial functioning and quality of life
47 48	302	Apathy. We use three items of the Geriatric Depression Scale (GDS-15) to assess apathy (sensitivity of
49 50 51	303	69% and specificity of 85%). These items include the following questions: 1) 'Do you prefer to stay at
52 53	304	home, rather than going out and doing new things', 2) 'Have you dropped many of your activities and
54 55	305	interests?', and 3) 'Do you feel full of energy'. A score of >2 points is classified as 'apathy present'. $^{43}$
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Social network and informal care. Participants are asked if they receive informal care, how many
hours a week, what type of care (housekeeping and/or personal care) and from which persons
(partners, children, other family members or neighbours/volunteers).

309 *Health-related quality of life.* This will be measured by the EuroQoL-5D (EQ-5D). The EQ-5D is a

310 broadly used and validated instrument for measuring generic health-related quality of life.<sup>36</sup>

311 4. Physical functioning

Risk of functional decline. Patients are assessed for risk of functional decline using the Identification
of Seniors at Risk- Hospitalized Patients (ISAR-HP) tool; scores of two and up indicate an increased
risk for functional decline.<sup>44</sup>

Functioning level. The 15-item modified Katz-ADL score is used to measure ADL functioning. This
 includes statements about independence in performing basic activities of daily living (ADL) and in
 instrumental activities of daily living (IADL).<sup>45,46</sup> We measure the Katz-ADL both currently (at
 admission), as well as two weeks before admission, reflecting pre-morbid level of functioning. The
 Katz-ADL is also measured during follow-up.

320 (Im)mobility. Mobility is assessed by reviewing three questions that are in the admission assessment
 321 regarding: 1) the use of a walking aid, 2) being able to walk outside of the house for five minutes (two
 322 weeks before and currently) and 3) the performance and frequency of physical activity.<sup>47</sup>

Handgrip strength. Measure muscle weakness is measured by physiotherapists in all admitted patients
 323 Handgrip strength. Measure muscle weakness is measured by physiotherapists in all admitted patients
 324 using the maximum handgrip strength (Jamar). 48

325 *Gait speed.* Gait speed is measured as part of the Short Physical Performance Battery (SPBB), which is 32 33 326 part of the physiotherapists' admission assessment.<sup>49</sup>

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2 3	327	<i>Falls.</i> Fall history is assessed by asking about the number of falls in the past six months. <sup>41</sup> During the
4 5		
6	328	discharge assessment, the occurrence of falls in the AGCH and the consequences of falls (indication
7 8 9	329	for prolonged stay, diagnostics or injury) are recorded.
10 11 12	330	Fear of falling. The Numeric Rating Scale (NRS, score 0-10) is used to assess the fear of falling; 0
13 14	331	indicates no fear of falling, and 10 indicates the greatest fear of falling possible. <sup>34</sup>
15 16 17	332	<i>Pain.</i> The standard clinical measure for pain is the NRS, ranging from 0 to 10, in which a score of 0
18 19 20	333	represents no pain and 10 represents the worst possible pain. <sup>50</sup>
21 22	334	Fatigue. A NRS from 0-10 is used, with 0 indicating no fatigue and 10 indicating the greatest fatigue
23 24 25	335	ever felt by the participant. <sup>51</sup>
26 27 28	336	Sleep. Participants are asked if they have had difficulties with sleeping in the past month and
29 30	337	whether participants have used sleep medication.
31 32 33	338	Nutrition. We will use the Short Nutritional Assessment Questionnaire (SNAQ) to identify patients
34 35	339	with malnourishment. The SNAQ consists of three questions concerning weight loss, appetite and
36 37 38	340	drink/tube nutrition, resulting in a score ranging from 0 to 5. Scores of 0 and 1 are defined as 'no
39 40	341	malnutrition', 2 as 'moderate malnutrition' and 3 or more as 'severe malnutrition'. <sup>52</sup>
41 42 43	342	5. Healthcare utilization and satisfaction with care
44 45 46	343	Medical care during admission and the process of discharge. The following items are collected from
47 48	344	patients' electronic health records: the diagnostics performed in the AGCH, revisits to the hospital,
49 50 51	345	admissions to the hospital, length of stay at the AGCH, discharge destination and time needed to
52 53	346	send medical handovers to the general practitioner.
54 55 56	347	Hospital readmission. This outcome will be assessed during follow-up. Follow-up will consist of three
57 58	348	telephone interviews at one, three and six months after discharge. Readmission will be both assessed
59 60	349	during the follow-up interviews and by checking care data from an aggregated database of expense

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3 4	350	claims from various healthcare insurers. Data that will be collected are as follows: number of
5 6	351	readmissions, total days of readmission, reasons for readmission and whether the readmission was
7 8 9	352	planned or unplanned.
10 11 12	353	Emergency department (ED) visits. ED visits will be assessed during follow-up and checked in the
13 14 15	354	insurance data. We will record the number of separate ED visits.
15 16 17	355	Outpatient hospital visits. We will ask patients if there have been any outpatient visits in the past
18 19 20	356	month(s), and if so, how many.
21 22	357	Consultations by general practitioners. We will ask patients if, and how many times, they have
23 24 25	358	consulted with their general practitioner (both during the day and during out-of-office hours).
26 27	359	Consultations by physiotherapists or dieticians. We will ask patients if, and how many times, they
28 29 30	360	have consulted with a physiotherapist or dietician in the past month(s).
31 32 33	361	Home care. This includes questions on the frequency of home care, including housekeeping, personal
34 35	362	care and nursing care. We will also include hours of informal care provided by family members or
36 37 38	363	friends.
39 40	364	Temporary admission to a nursing home. This includes days of (temporary) admission to a skilled
41 42 43	365	nursing facility or rehabilitation facility.
44 45 46	366	Permanent institutionalization. This concerns long-term admission to a skilled nursing facility and the
47 48 49	367	date of admission to this facility.
50 51	368	Patient satisfaction with care. Patients or informal caregivers are asked to fill out an 8-question
52 53	369	questionnaire regarding their satisfaction with the care that they received. Questions are answered
54 55 56	370	on a 5-point Likert scale. <sup>53</sup>
57 58 59 60	371	

3 4 5	372	Sample size calculation
5 6 7	373	In the Hospital-ADL study, 34% of participants experienced a readmission at 90 days. <sup>34</sup> Assuming that
8 9	374	26% of patients admitted to the AGCH will experience a 90-day readmission, data from 515 patients
10 11	375	at the AGCH will yield 80% power to detect an absolute difference of 8% in the readmission rate
12 13 14	376	(which is a 25% reduction in the relative risk) using a two-sided test with an alpha of 0.05. <sup>54</sup> As we
15 16	377	expect 10% loss to follow-up, we aim to include a total of 567 (= 515*1.10) patients from the AGCH.
17 18 19	378	
20 21 22	379	Planned statistical analyses
22 23 24	380	The complete participant flow diagram will show a summary of admissions and study recruitment at
25 26	381	the AGCH and will provide study discontinuation rates at one, three and six months follow-up. <sup>30</sup> We
27 28	382	will describe the demographic, clinical and prognostic characteristics of the study participants at
29 30 31	383	baseline. The number of participants with missing data will be collected and described alongside our
32 33	384	variables to check for the pattern of missingness. Inversely weighted propensity scores will be used
34 35	385	to control for any imbalances between the treatment groups. <sup>55</sup> Propensity scores will be calculated
36 37	386	using generalized booted methods. Balance and overlap of propensity score distribution will be
38 39 40	387	assessed. Propensity score weights for the estimation of the average treatment effect will be created
40 41 42	388	using all covariates where groups differed at baseline or that were associated with the 90-day
43 44	389	readmission rate. As this is a repeated measures design, we will assume equal weighting for all
45 46 47	390	measurements. <sup>56</sup>
48 49	391	All hypotheses will be tested using a two-tailed significance level of 0.05. All secondary outcomes will
50 51	392	be adjusted for multiple testing using a Hochberg method. <sup>57,58</sup> Descriptive analyses will be performed
52 53 54	393	to examine the participants' characteristics. Differences in changes over time in outcomes will be
55 56	394	compared between groups using multilevel models. All models will include a main effect of
57 58	395	treatment group, a linear term for time and an interaction between time and treatment group.
59 60	396	Models will be checked with residual and appropriate goodness-of-fit statistics.

1 2		
2 3 4	397	
5 6 7	398	Economic evaluation
7 8 9	399	A healthcare and societal perspective is planned for the economic evaluation. The evaluation from
10 11	400	the healthcare perspective will only include direct medical costs accrued in the six months after the
12 13	401	admission to the AGCH. Direct medical costs will only include costs that are funded through the
14 15 16	402	Dutch healthcare system. The evaluation from a societal perspective will include an estimation of the
17 18	403	costs of informal care. Costs will be based on the reference prices found in the Dutch Manual for
19 20	404	Costing studies and will be set for the final year of data collection (2020 or 2021). According to this
21 22 22	405	guideline, costs will be discounted at 4% and quality adjusted life years (QALY) will be discounted at
23 24 25	406	1.5%. <sup>59</sup> Propensity scores will also be used in the economic evaluation. Missing data will be imputed
26 27	407	using multiple imputation chained equations, if necessary, for the cost and effect data. We plan to
28 29	408	use generalized linear regression models with a gamma distribution and an identity link to account
30 31	409	for the right skew of the cost data. A generalized linear regression model will be used to estimate the
32 33 34	410	incremental effect in QALY adjusted for baseline utility estimates with a Gaussian distribution and
35 36	411	identify link. <sup>60</sup> Incremental cost-effectiveness ratios will be calculated using the pooled cost and
37 38	412	effect estimates. Bootstrapped cost-effect pairs will be plotted on a cost-effectiveness plane and
39 40	413	used to estimate cost-effectiveness acceptability curves. <sup>61</sup>
41 42 43	414	Process evaluation and patient experience
44 45	415	Process evaluation and patient experience
46 47	416	We plan to use a qualitative study design to describe the barriers and facilitators to implementation
48 49 50	417	of the AGCH concept and describe the experiences of the patients and healthcare professionals with
50 51 52	418	the AGCH. We will conduct semi-structured interviews with various stakeholders, such as
53 54	419	geriatricians, nurses, physiotherapists and hospital administrators. These interviews will concern the
55 56	420	implementation of the AGCH concept. In addition, semi-structured interviews with patients and
57 58 59	421	informal caregivers will be conducted in order to describe the patient experience and satisfaction
60	422	with this new form of care. A representative sample of patients and/or caregivers who participate in

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the prospective cohort study will be approached and invited to be interviewed shortly after discharge from the AGCH. Stakeholders and healthcare professionals will be selected by a researcher and will be invited for an interview to discuss their experiences and opinions on the AGCH. Interviews will be typed verbatim and analysed independently by two researchers using thematic analyses.<sup>62</sup> In our analysis of the barriers and facilitators to implementation, we will describe these factors at three different levels: micro (healthcare professionals), meso (care organizations) and macro (legal and financial framework).<sup>63</sup> The findings will be summarized in matrices with the facilitators and barriers at these three different levels and can be used to develop a guideline for implementation of the AGCH elsewhere.64

## **Preliminary results**

Between February 1<sup>st</sup> and December 20<sup>th</sup>, 2019, there were 362 consecutive admissions to the AGCH. Of these admissions, 26 were readmissions of patients who were already study participants. Of the remaining 336 admissions, 90 were by patients who did not meet the inclusion criteria. The remaining 246 patients or legal representatives and healthcare-proxy were approached for participation; 212 consented to participation (figure 2). The healthcare-proxy provided informed consent in 62 (29.2 %) of cases. Sixteen patients did not consent to follow-up by telephone but did consent to medical record review. The total study sample as of December 20th, 2019, consisted of 212 participants at baseline. Table 2 displays the baseline characteristics of this group. Participants had a mean age (standard deviation) of 81.8 (8.4) years and 47.6 % were male. Most participants were living independently before admission (81.1%). The most frequent admission diagnoses were infectious diseases (28.3%, mostly urinary tract infections), respiratory-related diseases (25.5%, of which half were pneumonia), and other (geriatric) diagnoses such as falls, delirium or sudden unexplained functional decline (30.2%). The main cardiovascular (9.4%) admission diagnosis was

1 2		
- 3 4	447	exacerbation of heart failure. The median (interquartile range) length of stay was 8.0 days (5.0-12.0),
5 6 7	448	and 83.7 % of patients were discharged to their original living situation.
7 8 9	449	
10 11 12 13 14	450	Discussion
14 15 16	451	The complex acute medical needs of older patients require the delivery of specialized geriatric care.
17 18	452	The traditional hospital environment may however not support recovery and maintaining
19 20	453	independence. The AGCH aims to deliver care that focuses on medical treatment, early rehabilitation
21 22	454	and proper transitions of care for older adults with multiple chronic conditions. <sup>29,65</sup> The AGCH is
23 24 25	455	unique in the Netherlands in its aim to combine multiple evidenced-based components of care for
26 27	456	frail older persons at an alternative location for hospital care. The proposed research will provide
28 29	457	insight into the clinical and economic effectiveness of care delivered at the AGCH, compared to
30 31 32	458	hospital care.
33 34 35	459	Our preliminary results show that data collection at the AGCH is feasible and we expect to recruit
36 37	460	enough patients to evaluate the primary outcome. There are also limitations to the design of this
38 39	461	study. It is a non-randomized study and historic cohorts are used as control groups. Therefore,
40 41	462	baseline differences between the intervention and control groups may hamper the matching
42 43 44	463	between the groups. Additionally, the data from the historic cohorts were not collected in the same
45 46	464	time period as the AGCH cohort. This is a limitation as work processes in hospitals may have changed
47 48	465	over the years, which could influence our results. However, the two control populations do represent
49 50	466	a geriatric population that was admitted for exacerbations of chronic conditions and acute illnesses
51 52	467	that frequently occur in older persons. The strengths of the study are the involvement of patients
53 54 55	468	and informal caregivers in the design of the concept of the AGCH. Moreover, a process evaluation
56 57 58 59 60	469	will address the barriers and facilitators to implementation of the AGCH in the Dutch Healthcare

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3 4	470	system. In short, this research will provide valuable insights into the implementation of this concept
5 6 7	471	of care in other regions of the Netherlands and abroad.
8 9 10	472	Ethics and Dissemination
11 12 13	473	This study will be carried out in accordance with the Declaration of Helsinki and current ethical
14 15	474	requirements. The outcomes of this study will be reported according to the STROBE guidelines for
16 17 18	475	cohort studies. <sup>30</sup> This study will evaluate both the effectiveness of this type of care delivery and the
19 20	476	costs that are involved, allowing for the system to be implementation elsewhere. The findings of this
21 22	477	study will be published in peer-reviewed journals.
23	478	
24	479	Acknowledgements
25 26	480	The authors thank all the (care) professionals from the Amsterdam University Medical Centres,
27	481	Cordaan and Zilveren Kruis who have worked on the development of the AGCH. Thank you for your
28	481	time, advice and cooperation. We would also like to thank the members of the AGCH study group,
29		
30 31	483	which are the clinicians who work at the Geriatrics Department of the Amsterdam University Medical
32	484	Centres and who support the data collection at the AGCH.
33	485	
34	486	Author contributions
35	487	MER, JMV and RS contributed to the design of the protocol and drafting of the manuscript. IO and
36 37	488	BMB made substantial contributions to the design and clinical aspects of the protocol. BMB
38	489	conceived the study and wrote the funding applications. All authors critically revised the manuscript
39	490	and approved the final version of this manuscript.
40	491	
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55	502	
56		Ethics approval
57 58	504 505	Ethics approval Reserved on the study protocol, the Ethics Committee (METC) of the Amsterdam University Medical
58 59	505 506	Based on the study protocol, the Ethics Committee (METC) of the Amsterdam University Medical
60	506	Centre waived the obligation for the study to undergo formal ethical approval as is described under

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3	507	Dutch	law in the Medical Research in Humans Act, January 2019 (ref W17_474 # 19.001). As this is a				
4	508	prospe	ective study and pseudonymised data is used, written informed consent was obtained from the				
5 6	509		pants prior to participation. This is in line with current European legislation under the General				
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8	510	Dala P	rotection Regulation (GDPR).				
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Figure 1 Patient admission process and criteria, components of the AGCH intervention and goals.

#### (uploaded separately as an image) CGA= Comprehensive Geriatric Assessment<sup>29</sup> **GP=** General Practitioner

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Figure 2 Diagram of patient	participation between Februar	y $1^{st}$ and December 20 <sup>th</sup> , 2019.
	participation between rebraa	

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<b>Table 1</b> Overview of the content and description of the (outcome) measurements and timing of the
measurements at the Acute Geriatric Community Hospital.

	Description and/or instrument	H1	H2	P1	P3	Pe
1. Medical and demogr						
Sociodemographic data	Date of birth, age at admission, sex, level of education, living conditions,	R				
	marital status					
Data on admission	Time spent at the ED, admission diagnosis, date and time of admission	R				
Chronic conditions	Charlson Comorbidity Index <sup>38</sup>	R				
Polypharmacy	Number of drugs	R				
Mortality	Date of death		R	R	R	R
2. Cognitive functioning	1					
Cognitive impairment	Mini-Mental State Examination (MMSE) <sup>31</sup>	R				
Delirium	Safety management system patient screening (VMS) <sup>41</sup> Confusion Assessment Method (CAM) <sup>39</sup> Delirium Observation Scale (DOS) <sup>42</sup>	N/ D	N/ D			
3. Psychosocial function						
Apathy	Geriatric Depression Scale (GDS-3) <sup>43</sup>	Ν	R	R	R	R
Social network and	Presence and frequency of informal	R		R	R	R
informal care	care					
Quality of life and health status	EQ-5D <sup>36</sup>	R		R	R	R
4. Physical functioning						
Identifying at-risk-	ISAR-HP- Identifying Seniors at Risk score <sup>44</sup>	N				
Functional status	Activities of daily Living (ADL) modified Katz-ADL score <sup>35</sup>	N				
(Im)mobility	Using a walking aid, information from the Katz-ADL questions on exercise	N				
Handgrip strength	Jamar <sup>48</sup>	Р				
Gait speed	Short Physical Performance Battery (SPPB) <sup>49</sup>	Р	2			
Falling	Fall history Falls in the AGCH	N	R	R	R	R
	Numeric Rating Scale (NRS) on the fear of falling <sup>34</sup>	N	R	R	R	R
Pain	Numeric Rating Scale (NRS) on pain <sup>50</sup>	Ν	R	R	R	R
Fatigue	Numeric Rating Scale (NRS) on fatigue	N	R	R	R	R
Nutrition	Short Nutritional Assessment Questionnaire (SNAQ) <sup>52</sup>	N				
5. Healthcare utilization	n and satisfaction with care					1
Medical care during admission	Diagnostics performed in the AGCH Readmission to university hospital Length of stay at the AGCH		R			

Hospital readmission	Readmission rate to the hospital or AGCH		R	R	R	R
Health care utilization	Home care, medical specialist care, temporary institutional care, primary care	R		R	R	R
Satisfaction with Care	Eight question questionnaire <sup>53</sup>		R	(R) *		

H1= at admission, H2= at discharge, P1= one month after discharge, P3 = three months after discharge, P6 = six months after discharge. N=nurse Geriatric Community Care Hospital, P= physiotherapist, D= Doctor/attending physician, R= researcher/research nurse. \*in case the assessment was missed at H2.

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# Table 2 Baseline characteristics of the study participants

Variable	N=212
Age in years, mean (SD)	81.8 (8.4)
Male, N (%)	101 (47.6)
Living arrangements before admission, N (%)	
Independent	172 (81.1)
Assisted living/senior residence	31 (14.6)
Nursing home/other	9 (4.2)
Marital status, N (%)	
Widow/widower	94 (44.5)
Married or living together	71 (33.6)
Single or divorced	46 (21.8)
Education, N (%)	
Primary school	36 (18.7)
Elementary technical/domestic science school	41 (21.2)
Secondary vocational education	65 (33.7)
Higher level high school/third-level education	51 (26.4)
Born in the Netherlands, N (%)	158 (76.0)
Katz-ADL (6 item) score <sup>a</sup> upon admission, median (IQR)	3.0 (1.0-5.0
MMSE score <sup>b</sup> , mean (SD)	23.7 (4.7)
Polypharmacy <sup>c</sup> , N (%)	159 (75.0)
Hospitalization in past 6 months, N (%)	61 (31.1)
Charlson Comorbidity Index <sup>d</sup> , mean (SD)	2.8 (2.0)
Primary admission diagnosis, N (%)	
Infectious diseases	60 (28.3)
Respiratory (including pneumonia)	54 (25.5)
Gastrointestinal	9 (4.2)
Cardiovascular	20 (9.4)
Neurologic	16 (7.5)
Other (e.g., falls, delirium, sudden unexplained functional decline)	53 (30.2)

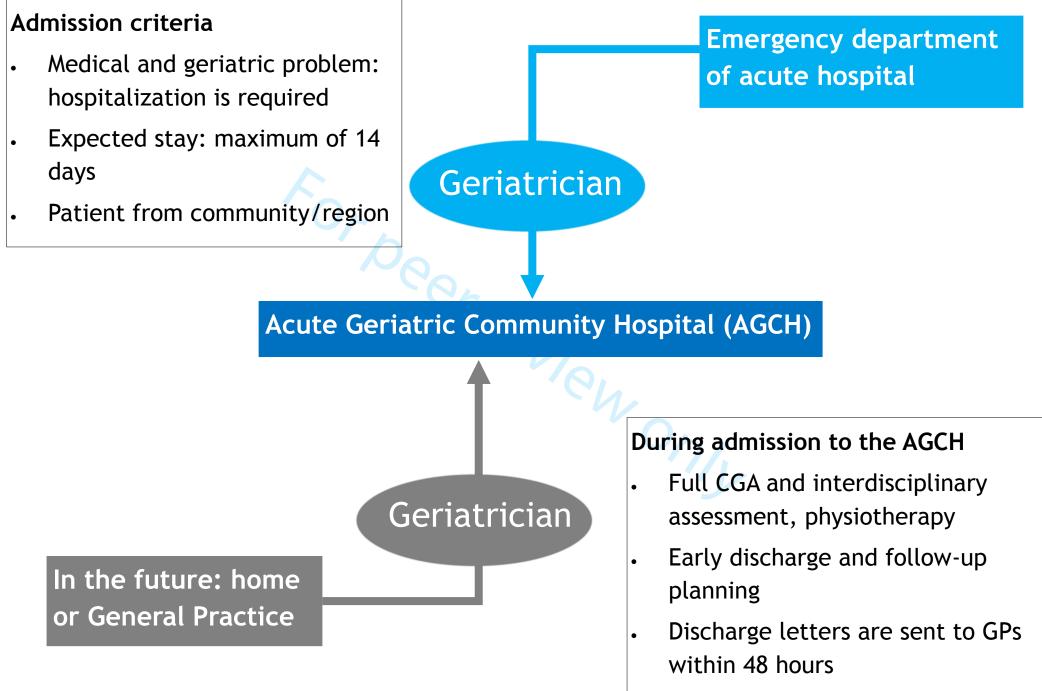
SD, standard deviation; IQR, interquartile range

<sup>a</sup>Score ranging from 0-6, with a higher score indicating more dependence in activities of daily living<sup>35</sup> <sup>b</sup>Score ranging from 0-30, with a score of ≤23 indicating possible cognitive impairment <sup>31</sup>

<sup>c</sup>Use of 5 drugs or more

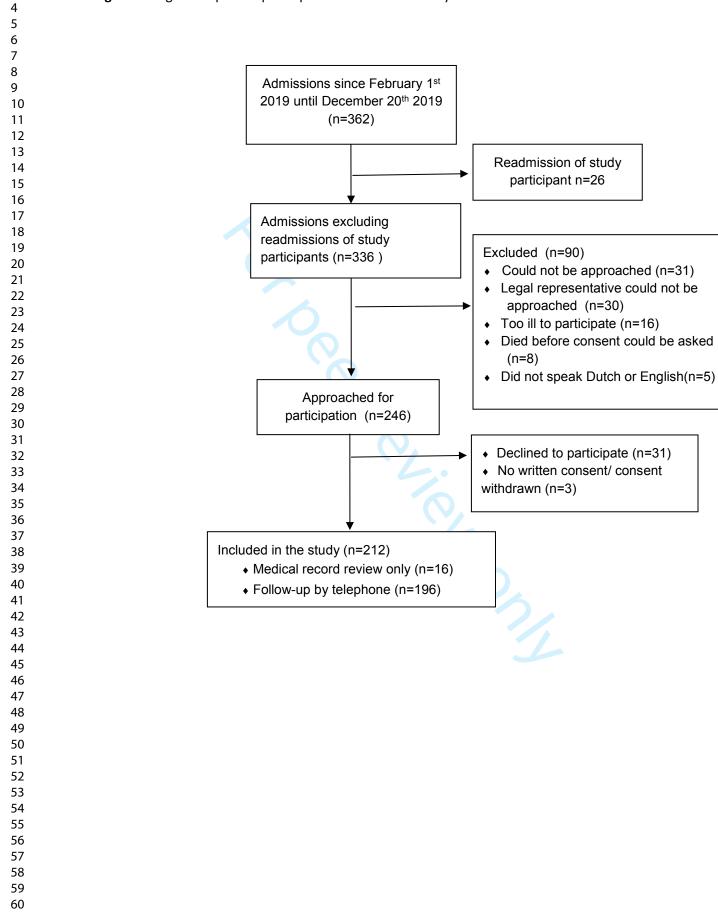
<sup>d</sup>Ranging from 0-31, with a higher score indicating more severe comorbidity<sup>38</sup>

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# **Figure 2** Diagram of patient participation between February 1<sup>st</sup> and December 20<sup>th</sup> 2019.



**Supplementary table** Overview of the content and description of (outcome) measurements and timing of measurements at the Acute Geriatric Community Hospital compared to the measurements available in the two control groups.

	Description and/or instrument	H1	H2	P1	P3	P6
1. Medical and demogr	aphical data					
Sociodemographic	Date of birth, age at admission, sex,	ΤА				
data	level of education, living conditions,					
	marital status					
Data on admission	Time spent at the ED*, admission	ТА				
	diagnosis, date and time of admission					
Chronic conditions	Charlson Comorbidity Index <sup>38</sup>	ΤА				
Polypharmacy	Number of drugs	ΤА				
Mortality	Date of death			Т	A	
2. Cognitive functioning						
Cognitive impairment	Mini Mental State Examination	ΤА				
0	(MMSE)					
Delirium	Safety management system patient	Т				
	screening (VMS) <sup>41</sup>					
	Confusion Assessment Method	$TA^{\dagger}$				
	(CAM) <sup>39</sup>	T <sup>†</sup>	т			
	Delirium Observation Scale (DOS) <sup>42</sup>					
3. Psychosocial function						
Apathy	Geriatric Depression Scale (GDS-3) <sup>43</sup>	А	А	А	А	
Social network and	Presence and frequency of informal	Т	_	-	-	Т
informal care	care					
Quality of life and	EQ-5D <sup>36</sup>	ΤА		А	А	ТА
health status						
4. Physical functioning						
Identifying at-risk-	ISAR-HP- Identifying Seniors at Risk	Т				
patients	score <sup>44</sup>					
Functional status	Activities of daily Living (ADL) modified	ΤΑ Α		А	А	Т
	Katz-ADL score <sup>35</sup>					
(Im)mobility	Using walking aid, information from	ТА	ТА			
()	the Katz-ADL questions on exercise					
Handgrip strength	Jamar <sup>48</sup>	ΤΑ Α				
Gait speed	Short Physical Performance Battery	ТА	A			
	SPPB <sup>49</sup>					
Falling	Fall history	ТА	-	А	А	т
	Falls in the AGCH	n/a	n/a	n/a	n/a	n/a
	Numeric Rating Scale (NRS) on the	A	A	A	A	-
	fear of falling <sup>34</sup>					
Pain	Numeric Rating Scale (NRS) on pain <sup>50</sup>	ТА	А	А	А	
Fatigue	Numeric Rating Scale (NRS) on	ТА	A	A	A	
	fatigue <sup>51</sup>					
Nutrition	Short Nutritional Assessment	ТА				
	Questionnaire (SNAQ) <sup>52</sup>					
5. Healthcare utilization	and satisfaction with care			1		1
Medical care during	Diagnostics performed in the AGCH		n/a	_		
admission	Readmission to university hospital		n/u			

	Length of stay at the AGCH					
Hospital readmission	Readmission rate to the hospital or AGCH			А	ТА	Т
Health care utilization	Home care, medical specialist care, temporary institutional care, primary care.	Т		A	A	т
Satisfaction with Care	Eight question questionnaire <sup>53</sup>		-	-		

Grey tone= measurement in prospective cohort study at the AGCH.

H1= at admission, H2= at discharge, P1= one month after discharge, P3 = three months after discharge, P6 = six months after discharge.

T= available from Transitional Care Bridge study(TCB)<sup>1</sup>

A= available from Hospital- ADL study(H-ADL)<sup>2</sup>

\* and - =Not available from TCB or H-ADL

ore true on t <sup>+=</sup>Single baseline measurement

n.a.= not applicable

# Appendix 1 STROBE statement checklist

STROBE Statement—Checklist of items that should be included in reports of cohort studies

	ltem No	Recommendation	Item found on page
Title and abstract	1	( <i>a</i> ) Indicate the study's design with a commonly used term in the title or the abstract	1 and 3
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 3
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 5-7
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 7
Methods		0	
Study design	4	Present key elements of study design early in the paper	Page 8 -9
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow- up, and data collection	Page 7-15
Participants	6	( <i>a</i> ) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up	Page 7-10 and 11
		(b) For matched studies, give matching criteria and number of exposed and unexposed	Page 9 and 10
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 11 – 15
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 11-15 (supplementary table)
Bias	9	Describe any efforts to address potential sources of Page 16 bias	
Study size	10	Explain how the study size was arrived at	Page 16
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 16

Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 16
		(b) Describe any methods used to examine subgroups and interactions	n/a
		(c) Explain how missing data were addressed	Page 16
		( <i>d</i> ) If applicable, explain how loss to follow-up was addressed	Page 16
		( <u>e</u> ) Describe any sensitivity analyses	n/a
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 18 and 26 (figure 2)
		(b) Give reasons for non-participation at each stage	Page 18 and 26 (figure 2)
		(c) Consider use of a flow diagram	Page 26, figure 2
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 18,19 and 2
		(b) Indicate number of participants with missing data for each variable of interest	n/a
		(c) Summarise follow-up time (eg, average and total amount)	n/a
Outcome data	15*	Report numbers of outcome events or summary measures over time	n/a
Main results	16	( <i>a</i> ) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	n/a
		(b) Report category boundaries when continuous variables were categorized	Page 29
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	n/a
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	n/a

Discussion			
Key results	18	Summarise key results with reference to study objectives	Page 19
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Page 19
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 19
Generalisability	21	Discuss the generalisability (external validity) of the study results	n/a
Other information		6	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 20

\*Give information separately for exposed and unexposed groups.

**Note:** An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at http://www.strobe-statement.org.