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Data resource profile: the virtual international care homes trials archive (VICHTA)

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Abstract

Introduction
Randomised controlled trials (RCTs) conducted in care home settings address a range of health conditions impacting older people, but often include a common core of data about residents and the care home environment. These data can be used to inform service provision, but accessing these data can be challenging.

Methods
The Virtual International Care Home Trials Archive (VICHTA) collates care home RCTs conducted since 2010, with >100 participants, across multiple conditions, with documented eligibility criteria, initially identified from a scoping review. A Steering Committee comprising contributing trialists oversees proposed uses of fully anonymised data. We characterised available demography and outcomes to inform potential analyses. Data are accessible via application to the Virtual Trials Archives, through a secure online analysis platform. Trial recruitment is ongoing and future expansion will include international studies.

Results
The first phase of VICHTA includes data from six UK RCTs, with individual participant data (IPD) on 5,674 residents across 308 care homes. IPD include age, sex, dementia status, length of stay, quality of life, clinical outcome measures, medications, resource use, and care home characteristics, such as funding, case mix, and occupancy. Follow-up ranges between four and sixteen months.

Conclusions
VICHTA collates and makes accessible data on a complex and under-represented research population for novel analyses, and to inform design of future studies. Planned expansion to international care home RCTs will facilitate a wider range of research questions. Interested collaborators can submit trial data or request data at www.virtualtrialsarchives.org.

Keywords
older adults; care homes; randomised controlled trials

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Key features

Why: The Virtual International Care Homes Trials Archive (VICHTA) was created to address the growing need for research in care home settings, driven by the global phenomenon of population aging and an increasing demand for long-term residential care. The collaboration aims to facilitate secondary research, improve care and interventions in care homes, and inform policy and practice to better cater to the needs of the older adult population residing in care homes
Uniqueness: VICHTA combines clinical trials conducted within older adult care home settings. This approach allows for a comprehensive examination of residents' characteristics, care quality, environmental factors, and social care priorities, providing a holistic view of care homes and their populations.
Details: VICHTA currently comprises data from six randomised controlled trials (RCTs) involving 5,674 residents residing in 308 care homes in the United Kingdom. The dataset predominantly consists of females, with a median age of 86, and a significant portion had a known dementia diagnosis at baseline. The dataset covers a wide range of demographic and clinical characteristics of care home residents.
Data: The dataset within VICHTA encompasses various categories of data, including: Demographic and clinical characteristics of care home residents; Outcome measures collected through proxy responses from care home staff; dementia-specific assessments, and functional ability measurements; health resource use, and medication data.
Access: Researchers interested in accessing the VICHTA dataset can do so by submitting research proposals through the Virtual Trials Archive (VTA) website: www.virtualtrialsarchives.org. It follows a managed-access model, with a Steering Committee (SC) overseeing the approval process for data access. The data requester is permitted access to VTA online data platform where anonymised dataset is held and all analysis performed.

Background

Population ageing is a global phenomenon that impacts much of the developed world. This demographic shift signals an increasing need for long-term residential care in coming decades. Care homes (defined here as facilities providing 24-hour care with- and without registered nursing staff [1]) represent one model to meet this demand. As of 2023, there are an estimated 430,000 people living in care homes in the UK [2].

Care homes represent a distinct and specialised care setting with unique challenges and characteristics. Research that focuses on community-dwelling individuals may not adequately represent care home residents, who often have higher levels of physical dependency and/or cognitive impairments [3]. There is often a disconnect in information sharing between care homes and other healthcare providers – this lack of integration hinders the flow of essential data and knowledge [4]. As the care home market is predominately private, different facilities have different systems for data management and reporting, making it challenging to gather comprehensive and standardised information. Due to the lack of data and uniqueness of the care home population, there is a need to build an evidence base specially tailored to the care home setting to inform appropriate care and interventions.

Care homes are increasingly a setting within which randomised controlled trials (RCTs) are being conducted. These trials collect high quality, anonymised data, at both institutional and individual resident levels. While they may focus on a variety of topics (e.g. infection, falls risk, medication management, or nutrition) the care home population is often assessed using common outcome measures. Individual participant data (IPD) in trials refers to the specific, raw information collected for each participant, encompassing demographics, medical history, treatment details and outcomes. Quantitative IPD collected from these participants and homes have the potential to be pooled and used in secondary or novel analysis. With increased sample size and statistical power, this represents an opportunity to consolidate much-needed epidemiological information on a population with complex health and social care needs in the last year(s) of life, as well as the chance to evaluate the sensitivity, relevance, and usability of assessment tools used in this population. This strategy is in line with ongoing efforts to enhance research efficiency and reducing research waste [5]. The International Committee of Medical Journal editors is committed to improve trial transparency by urging the sharing of quantitative IPD from such RCTs and registries [6], and work towards standardising the practice of sharing de-identified trial data [7]. Furthermore, the initiative has received support from UK Clinical Trials units [8] and care home researchers [9].

The Virtual International Care Homes Trials Archive (VICHTA) is a repository of RCTs conducted in older adult care homes, to which trials can continually be added. It was established to exploit the large amount of information collected about care homes and their residents in randomised controlled trials, with the potential to be pooled and repurposed for secondary research. Here we provide an overview of the initial phase of VICHTA, including how initial trials were identified and combined, data availability from early trials, and examples of potential secondary uses [10].

Methods

The Virtual International Care Home Trials Archive (VICHTA) uses a managed-access model and is a new sub-section of Virtual Trials Archives (VTA) [11, 12]. Established in 2001, VTA is a not-for-profit collaboration hosted by the Robertson Centre for Biostatistics at the University of Glasgow, UK, bringing together multiple, large, international datasets from completed clinical trials on stroke, cardiovascular disease and renal transplantation research [11, 13]. Contributing trialists comprise Steering Committees (SC), and oversee proposed use of data.

Investigators can access data by submitting a research proposal on the VTA website (www.virtualtrialsarchives.org). Following approval by the Steering Committee, data extraction is tailored to the specific research question. The requesting investigator is then granted access to analyse the bespoke dataset on a secure analysis platform. Once the analysis is completed, the anonymised dataset is archived centrally. The VTA is funded by administrative charges per data request, which supports data curation, storage, continued development,

and day-to-day administration of the resource. VTA has a well-established governance infrastructure, with ability to host data securely on a working data-sharing platform, and expertise to manage future trial inclusion and data access requests.

Selection of trials

Trials eligible for inclusion in VICHTA meet the following criteria:

- Examination of any intervention, conducted exclusively in an older adult care home settings
- Minimum sample size of 100 residents
- Study completed since 2010
- Documented entry criteria
- Documented resident consent or consultee assent following approved ethics procedures

Trials that recruited a combination of community dwelling and care home residents are excluded. This decision was made to focus on the contextual relevance of care home settings, and to better understand how social and environmental factors may impact resident outcomes. Larger trials are prioritised to ensure the data are generalisable to the broader care home, and to reduce administrative burden of accessing numerous small trials. Trials completed before 2010 are excluded to enhance the comparability of trials, as modern trials are more similar in terms of study design, participant characteristics and outcome assessments used.

Key information is drawn from the original trial protocol, funders report, and standard study documentation such as case report form templates and statistical analysis plans, but if any issues were not dealt with from those sources, we sought clarification from the original trial team.

There are no specified exclusion criteria for VICHTA, however it is noted that for care home trials, residents admitted for short-term or respite stays, or receiving end-of-life care, are often ineligible.

A scoping review identified potential care home trials for inclusion. For the initial development, we invited larger (>400 participants) trials conducted in the United Kingdom. Recruitment of smaller and active trials is ongoing and as the archive develops, there is scope to include international studies.

Potentially eligible trials are added to a database. All communication with trialists is logged. We write to the original trialists, explaining the purpose of VICHTA and how it will operate. When possible, we leverage personal connections within the study team to introduce the project. If the trialist declines or does not respond to reminders, we log this dataset as unavailable. If the trialist responds positively, we arrange a meeting to provide a more detailed outline the project. For ongoing trials, the entire trial team is invited to this meeting, with a chance to ask further questions. If a trialist agrees to participate, the study sponsor will be asked to sign a data sharing agreement (DSA) covering the transfer, use and storage of their trial data. The DSA is established between University of Hertfordshire, University of Glasgow, and the trial sponsor organisation (typically another university or NHS trust).

Upon completion of the Data Sharing Agreement by all relevant parties, trial data managers (e.g. within Clinical Trials Units (CTU)) are asked to assist in preparing the trial datasets. As standard practice with individual participant data sharing models [14], only completely anonymised quantitative data are held in the repository, to minimise the risk of reidentification. We request that all data received will be fully de-personalised (such as converting 'date of birth' to 'age at randomisation'). Full instructions on de-identification and how to transfer securely are provided if necessary. The trial dataset, along with all accompanying files, is transferred in a zipped, password protected folder to University of Glasgow (UG)'s Robertson Centre for Biostatistics (RCB), using the University of Glasgow's File Transfer Protocol. The RCB hosts the data, with no specified termination date. All data are retained on their server and analysed solely within their secure analysis platform.

Pooled variables are created if data collected in trials are identical (e.g. Age, Sex), or sufficiently similar so that the data can be merged without misinterpretation or loss of context. Each trial dataset is examined for anomalies and discrepancies, such as invalid, out-of-range, or inconsistent items. Decisions on standardisation will be made by consensus decisions with the wider TSC or delegated groups e.g. trial statisticians.

Many outcome measures collect information on individual domains which are then combined to produce a single, composite outcome. We request all individual domain levels where possible. If the scoring was modified, we seek clarification from the respective trialists in the SC for their advice and interpretation on whether the composite outcome data should be removed or amended to enable pooling with other trial datasets. Further details are provided in the published protocol [10].

Data access

A central role in VICHTA is that of the Steering Committee (SC), made up of trialists who have contributed datasets (in the first instance JB, JD, PL, EMC, CS & DW). As new trials are added to the archive, new SC members will join. The SC act as gatekeepers and have the ultimate responsibility for all decisions regarding strategy, confidentiality, scientific matters and determining publication policy. At the proposal stage, SC members may declare an interest in joining the analysis team of a proposed project and take up active participation, thereby meeting criteria for co-authorship set out by many journals. All completed analyses are reviewed by the SC before submission. Active involvement from each SC member is encouraged but not essential, as data request decisions are made by a quorum.

The process for investigators to access VICHTA data is as follows (see also Supplementary Figure 1):

1. Data requester submits request via Virtual Trials Archive (VTA) website, defining data required and research question

2. VTA circulates proposal to SC via email, to assess data request submissions and recommend whether access to data should be granted

3. SC reviews proposal and replies to email their preference as
    i. permit access to trial data with no further involvement
    ii. permit access and collaborate on the project
    iii. reject access (citing reasons why)
4. VTA collates SC responses and decision based on quorum.
5. VTA compiles anonymised dataset, tailored to the specific research question
6. Data requester is permitted access to VTA online data platform where anonymised dataset is held and all analysis performed
7. Data requester writes up analysis and circulates it to VTA team before journal submission
8. VTA circulates paper to SC for comments
9. On completion, the anonymised data extract can no longer be accessed by the investigator but is archived centrally

All resulting publications using VICHTA data must include by-line "on behalf of the Virtual International Care Homes Trials Archive (VICHTA) Steering Committee". SC members making active contribution are given opportunity to be named co-authors.

All electronic data is stored securely on University of Glasgow servers and will not be transferred or copied to any other location. VTA has extensive experience in managing data in compliance with data protection and privacy legislation [10].

Results

Collating trials

VICHTA currently contains six RCTs, with individual participant data (IPD) on 5,674 residents in 308 care homes across England, Scotland and Northern Ireland. The earliest randomisation was March 2011 and most recent September 2019. The combined research cost for the six trials was £13.2M (2023 prices). These original trials tested interventions including dementia care delivery and symptom management, polypharmacy, falls prevention and incontinence (See Table 1). In addition to the six trials secured, three trials are in the process of joining.

To reduce burden on contributing centres, the VICHTA team checked data dictionaries in advance and flagged any potentially identifiable variables that should be removed or converted, and any data that was not needed (e.g. qualitative data and details on treatment fidelity checks that would be impossible to pool with other).

Key demographics and clinical characteristics

VICHTA contains data on care home residents with a median age of 86 (IQR 45.3-104.0) who are mostly female (4,077; 72%). The median follow-up duration was 228 days (IQR 149–394) and 1,370 (24%) residents died before study completion. Seventy-four percent of participants had a known dementia diagnosis at baseline. Key demographic and clinical characteristics are outlined in Table 1.

Follow-up in the studies ranged from four to sixteen months. Data were relatively complete, with little missing data. Common reasons for incomplete data included death during follow-up, transfer to another care home, and less commonly, withdrawn consent, care home withdrawing, or inability to complete assessments. A small number of anthropometric measures including weight, height, blood pressure, kidney function was measured in two of the six trials. Socioeconomic factors were generally not reported. One study documented residents' level of education, previous employment, and smoking status. Reporting on deprivation of liberty and end of life pathway was inconsistent in trials – often appearing in health resource use data, but not systematically recorded.

Care home characteristics include type of care (45% registered as residential only); number of beds (median 41, IQR 32–60); ownership (81% privately owned) and quality ratings from national care regulators. Additional data which could not be pooled included information on staffing, bed occupancy, adaptive equipment available and funding mix.

Outcomes data

Data from standardised outcome measures (Table 2) were generally collected with assistance of care home staff, and usually comprised proxy responses. Outcome data completed by residents themselves were limited. Two studies also collected a small number of proxy responses from relatives. The EQ-5D-5L [21] (proxy) was the predominant outcome measure, used in four of the six trials. This is consistent with EQ-5D being the preferred health-related quality of life instrument for economic evaluations by the UK National Institute of Health and Care Excellence. A range of dementia-specific measures, including DEMQOL, QUALID, Qol_AD, QUALIDEM, were used. Functional ability was measured in three trials using Barthel which reports basic activities like getting up from a chair or bed, personal hygiene, bathroom use, going outside, dressing and bowel control. All three trials implemented the modified Barthel, where scores range from 0 to 20, with lower scores indicating increased disability or dependency.

Health service and medication use

All six trials included an economic evaluation component and used a variant of the Client Service Receipt Inventory (CSRI) [22] to record information on resource use and costs alongside the trial. This data has not yet been pooled, but data elements of interest include GP, district nurse, inpatient stays, A&E and ambulance attendances. Additionally allied health services, assistive devices and equipment, diagnostics and tests, and mental health services were recorded in most trial datasets.

A care home resident's medication regime can provide valuable insights into their health status, medical conditions, and overall care needs. There is substantial data on medications in all included trials, which have not yet been pooled. Data elements of interest include medication

Table 1: Trial level information and data availability at baseline

	CAREMED [15]	CHIPPS [16]	ELECTRIC [17]	DCM-EPIC [18]	FINCH [19]	RESCARE [20]	Data availability at baseline
Trial level information							
Recruitment period	2011–12	2017–19	2018–19	2014–16	2016–18	2011–12	All
Budget (2023 prices)	£378,054	£2,510,418	£1,498,605	£2,992,957	£2,554,408	£3,219,996	All
Location	England	England, Scotland & Northern Ireland	England & Scotland	England	England	England	All
N Resident participants	826	WP6: 882; WP5 (Pilot): 41	408	Cohort 1: 726; Cohort 2: 261	1698*	832	5674
N Care homes	30	44	37	50	84	63	308
Follow up (months)	12	6	4	16	12	4	All
Intervention type	Medication management	Pharmacist review	Incontinence	Dementia, Person centred care	Falls prevention	Dementia, Challenging behaviour	All
Baseline resident demographics							
Age	X	X	X	X	X	X	5663
Sex	X	X	X	X	X	X	5664
Education levels				X			319
Ethnicity				X	X		726
Years living in care home	X		X	X	X		3796
Days follow-up	X	X	X	X	X	X	5674
Died during FU	X	X	X	X	X	X	5673
Type of care received	X	X			X		2557
Funding source				X	X		2255
Dementia diagnosis	X	X		X	X	X	5148
Falls history	X	X	X		X		3850
Medical history	X						819
Blood pressure	X						587
Kidney function (eGFR)	X						482
Continence pads use			X				408
Care home characteristics							
Care type (Residential, nursing, mixed or dementia)	X	X	X	X	X	X	308
Number of beds	X		X	X	X	X	264
Quality Rating (CQC)				X	X		134
Ownership (Private, Not for Profit, or Local Authority)					X	X	147
Funding mix (Self-funded, Local authority or NHS)				X	X		134
Occupancy levels				X	X		134
Other measures collected throughout trial							
Health resource use	X	X	X	X	X	X	Not yet pooled
Health professional visits	X	X	X		X	X	
Medications (all)	X	X			X	X	
Medications (condition specific)			X	X			

• IPD includes 41 residents with baseline data but not randomised. Trial N = 1,657.
• ResCare a subsidiary trial in larger programme, full title Challenge DemCare.

name, dosage, frequency, and some are mapped to UK British National Formulary. Assessment tools used to evaluate medication use in older adults are available, including STOPP (Screening Tool of Older Person's Prescriptions) [23] the Drug Burden Index (DBI) [24] and a study-specific alert for medications associated with high risk of falls. Prescribed medications reflect chronic conditions, comorbidities, polypharmacy, pain, cognitive function, mobility, allergies and adverse reactions. Dynamic factors like changes to dose, frequency and route of administration provide health status indicators through the course of each trial period. Availability of medication data for each trial is outlined in Table 1.

Clinical status and multimorbidity

Availability of clinical indicators such as hospitalisations, falls, and death rates are outlined in Table 1. The choice of indictors often depends on the intervention's focus. For instance, the ELECTRIC trial, targeting incontinence, uniquely measured 'volume of urine leaked over 24 hours'. How medical conditions are reported varied between trials (see Table 3). CAREMED employed ICD10 Level 3 descriptions [25], CHIPPS used the Charlson comorbidity index [26], and others opt for bespoke binary indicators for the most common diagnoses. Dementia diagnosis was reported in all trials except one.

Table 2: Data availability – outcome measures

Outcome measure	CHIPPS	ELECTRIC	EPIC	FINCH	RESCARE	Baseline data recorded	Timepoints available (months)
Outcome measures							
Barthel (Modified)	2713	408		7218		2907	0,1,3,6,9,12
Challenging Behaviour Scale					1490	832	0,4
Clinical Dementia Rating			1996		979	1575	0,4,6,16
Clinical Frailty Scale		408				408	0
Cohen-Mansfield CMAI			1999		2496	1575	0, 4,6,16
DEMQOL		1033	1990	6216		2823	0,1,3,4,6,9,12
DEMQOL SR				1301		370	0,3,6,9,12
EQ5D-5L	2196		1986	6390		3256	0,3,6,9,12,16
EQ5D-5L SR	272		936	1319		880	0,6,16
EQ5D-5L Rel			364			169	0,6,16
EQ5D-3L					832	1326	0,4
EQ5D-3L SR					658	1035	0,4
EQVAS	2189			6312		2498	0,3,6,9,12
EQVAS SR	252			1272		469	0,3,6,9,12
Minnesota		1351				399	0,3
MMSE	41	408				449	0,3
NPI			1972		983	1294	0,4, 6, 16
PAM-RC				6386		1680	0,3,6,9,12
QUALID			1997			743	0,6,16
QUALIDEM	78					40	0,3
QOLAD and QOLAD-CH			934		1490	1228	0,4,6,16

- References for Outcome measures listed in Supplementary Table 1.
- Default: Proxy response completed by care staff.
- SR:Self-report by resident; Rel: Relative reported on behalf of resident.

Potential secondary uses

By connecting data based on *setting of care* instead of a condition-specific/diagnosis-specific topic area, VICHTA expands the potential for secondary analysis of residents' and care home characteristics and allows a diverse range of research questions to be addressed including quality of life, quality of care, environmental factors and priorities from social care. Groups who have already expressed an interest in the data include outcomes measurement specialists, social care macroeconomists, and geriatricians with an interest in frailty and multimorbidity. Some illustrative examples of how VICHTA data could be utilised are listed below.

- **Long term trends in care homes:** The earliest VICHTA data was collected in 2011, and there is no stated deadline for accepting future studies. It is therefore feasible to compare (trial) resident characteristics such as demographics, general frailty or comorbidities over time. When inclusion criteria are expanded to include non-UK studies, international comparisons may also be made, permitting exploratory analysis to better understand the global care home population.
- **Identifying subgroups or events:** Treating residents as a homogenous group is not sufficient and more individualised information is required to understand and address their health and wellbeing [27]. Use of pooled data to generate larger sample sizes permits examination of resident subgroups such as those with greater or lower dependency levels, or combinations of multimorbidity. Additionally, events which may occur during trial follow-up, such as injurious falls, infections, or hospital stays, could be identified and residents' data could be monitored before and after such occurrences. Thus, secondary analysis of IPD allows for more complex and flexible analyses than is possible with only summary-level data.
- **Understanding care home markets:** In many countries, including UK, it is difficult to find consistent information about the often-fragmented care home market, including case mix, funding mix and ownership [28]. By recording snapshots of key care home infrastructure data since 2011, and linking it to individual residents' demographics and outcomes, these trials hold the potential to inform policy and practice.
- **Methodological research:** There is a strong opportunity for methodological research with VICHTA data. This could entail mapping groups of similar measures (such as cognitive assessments) or harmonising similar variables (such as quality of life indicators) [29, 30]. With access to larger datasets, it should also be possible to identify which outcomes are missing or inconsistently recorded, to inform the development of a more comprehensive core outcome set for care home residents [31]. There is also

Table 3: Data availability – Health conditions

Condition	CAREMED	CHIPPS	EPIC	FINCH
Long term conditions reported	**ICD10 Level 3 description**	**Charlson Comorbidity Index**	**Tailored list of specific conditions**	**Tailored list of specific conditions**
Anxiety and depression	X	X		
Arthritis	X	X		
Asthma	X	X	X	
Circulatory system	X	X	X	
COPD	X	X	X	
Dementia	X	X	X	X
Diabetes	X	X	X	X
Digestive system	X	X	X	
Endocrine, metabolic and nutritional	X	X	X	
Falls	X	X	X	X
Fractures	X	X	X	X
Hearing impairment	X	X		
Heart failure	X	X	X	X
Hypertension	X	X		
Kidney disease	X	X		
Mental and behavioural	X	X	X	
Musculoskeletal system	X	X	X	
Neoplasms	X	X	X	
Nervous system	X	X	X	
Non pressure wounds	X		X	
Osteoarthritis	X	X		
Respiratory system	X	X	X	
Stroke	X	X		X
Ulcers	X		X	
Urinary Conditions	X	X		
Vision impairment	X	X	X	

X denotes information recorded about specific long-term conditions.
ELECTRIC and RESCARE omitted from table as long-term conditions not directly linked to treatment (urinary conditions and dementia, respectively) were not reported.

scope for further data harmonisation of data domains, such as with medications and health resource use.

Discussion

The global population is ageing, as we see an increase in people living to an older age with comorbidities. Research into care homes is essential to meet the needs of this growing population. VICHTA offers a cost-effective and efficient mechanism to conduct secondary research in care home populations. We are aware of one IPD meta-analysis combining the US and Dutch nursing home data [32], but this is the first attempt to develop a care homes trials archive, to which new trials can continually be added. Ideally, as argued by ICMJE [14], sharing individual participant data from clinical trials will become standard practice, and future applications for funding should plan data sharing procedures prospectively. VICHTA can be the platform to repurpose all trials conducted in care home settings. As more trial datasets are added, VICHTA can be used as a benchmark to compare with emerging studies, and to identify gaps in existing knowledge and research areas requiring further investigation.

The VICHTA initiative does not aim to replace perspective data collection or RCTs. Instead, it provides an opportunity to maximise data use and prevent research waste, which is common across all healthcare settings. Only one of the included trials reported a statistically significant positive treatment effect with their proposed intervention: rather than focusing on the intervention, repurposing data for exploratory research ensures it is useful beyond neutral trial results. Use of pooled data in retrospective or exploratory analysis in such a manner allows better planning for perspective studies including optimisation of outcome assessments, data collection time points, and sample size requirements so that prospective studies are better designed, and less likely to fail due to issues such as recruitment problems or dropout rates.

VICHTA's focus on care home setting, rather than clinical area, offers a unique vantage point for research across a spectrum of disease. Residents often require assistance with daily living activities and may have various medical conditions or comorbidities. Taking a whole-person approach can allow us to learn more from the extensive work to improve the care and management of residents. Similarly, focusing on the care home setting allows for more comprehensive assessment of overall care practices and their impact on resident outcomes.

Care home trials capture not only data on medical conditions, but also social and environmental factors that can influence health and well-being in this specific population [33], as well as organisational and market factors, which are often commercially sensitive and difficult to access [28].

In the initial included trials there is a strong emphasis on HRQoL and dementia outcomes. A wide range of outcome measures are applicable to care home research [34], and we anticipate this will evolve with the inclusion of new studies, expanding data availability to encompass areas such as infection control or respiratory issues, particularly in light of COVID-19-related studies. The advance of research on core outcome sets, ensuring consistency in outcomes measured across different trials, aligns with VICHTA and will enhance data collation, comparability and overall research quality further [31].

The process of accessing IPD from completed trials relies heavily on goodwill of trialists, their data custodians and trial sponsors. Contributing centres may be hesitant to share data if the trial has been archived, or they are constrained by time or resource. Early in discussions, two trial centres felt they should be renumerated in completing the task of preparing datasets for inclusion. We had a small budget for all contributing trials while the archive was being set-up, but going forward any data contribution to VTA is unfunded. Investigators and CTUs should therefore make provisions for this in funding applications. Trial sponsors may be concerned about protecting intellectual property rights and participant confidentiality. One sponsor initially expressed concerns about the data's full anonymity, however, after providing further explanation and a breakdown of the variables requested, they agreed to take part. We experienced some delays in ratifying data sharing agreements, and in anonymised data being made available. In addition to delays in accessing data due to hesitation from contributing centres, there is a natural pause in combining multiple trials. IPD is typically not shared until the original trialists have published their main results, creating a time lag between trial ending data collection and their results being reported. Trial data is not available continuously for every year since 2011, and gaps to data collection are anticipated considering COVID-19 when a majority of primary data collection was suspended. The archive is not designed as a longitudinal resource, but these factors combined may hinder research exploring contemporaneous policy issues.

There are ongoing challenges in determining the representativeness of the participating care homes and residents compared to the wider care home population, reflecting the known issues that care homes that participate in research may differ from those who choose not to [35, 36]. This increase in sample size however mitigates some of these concerns. Planned analysis will compare VICHTA care homes recruited in England with publicly available data to assess generalisability [37–39]. Further plans for the archive include stakeholder engagement to establish what are the research priorities for care home residents, families, staff and commissioners, and importantly, if, and how, these could be answered using VICHTA data. Ultimately, our goal is to facilitate the development of more effective care home interventions, and better care for this vulnerable population.

Conclusions

As an extension of the Virtual Trials Archive, with established governance and a contributor-led Steering Committee, the VICHTA model repurposes anonymised care home trial data, facilitating novel research through a managed-access data-sharing platform. Currently encompassing six RCTs, VICHTA includes individual participant data from 5,674 residents across 308 UK care homes. Uniquely, the platform prioritises care-home setting over condition-specific focus, enhancing secondary analysis possibilities. Potential secondary uses include trend identification, subgroup insights, understanding the care home market, and methodological advancements. At low cost and minimal risk to future researchers, VICHTA can advance care home knowledge, impacting quality of care and informing policy and practice, showcasing the transformative power of repurposed RCT data. Investigators can access data by submitting a research proposal on the VTA website (www.virtualtrialsarchive.org).

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Ethics statement

Data sharing and pooling must adhere to ethical standards, safeguarding the privacy and confidentiality of care home residents' information. The project is sponsored by University of Hertfordshire, and their Ethics Review Board has approved this methodology (HSK/SF/UH/04185 approved 18 June 2020). Virtual Trials Archive has overarching university ethical approval for all their repositories and will update this through the University of Glasgow, including VICHTA.

Conflict of interests

Funded by NIHR Health Service & Delivery Research (HS&DR) DACHA project grant ref: NIHR127234.

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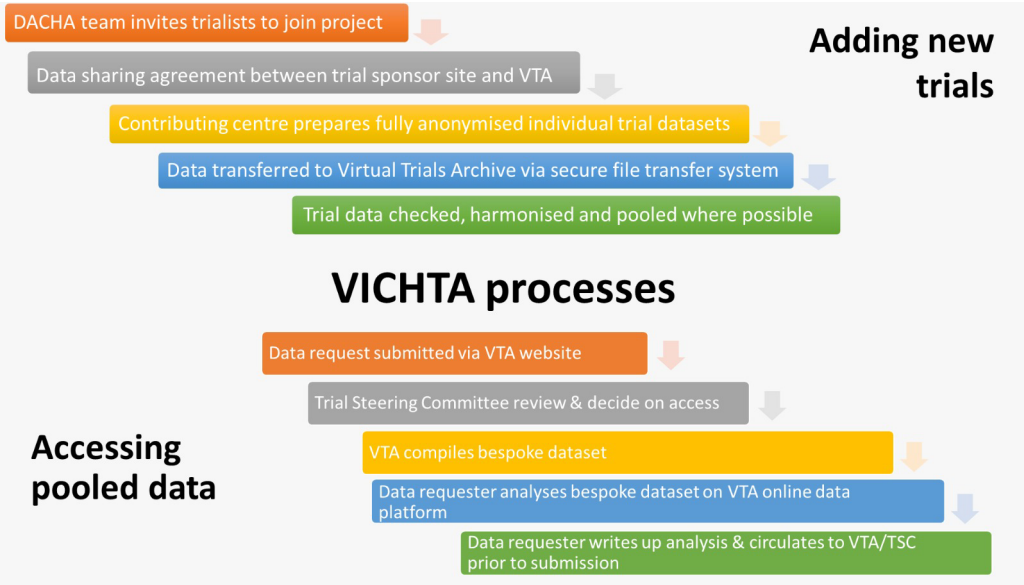
List of Abbreviations

CTU:	Clinical Trials Unit
DACHA:	Developing research resources And minimum data set for Care Homes' Adoption
IPD:	Individual participant data
RCB:	Robertson Centre for Biostatistics
RCT:	Randomised Controlled Trial
SC:	Steering Committee
VICHTA:	Virtual International Care Homes Trials Archive
VTA:	Virtual Trials Archive

Supplementary Figure 1: Flowchart for adding and accessing data



Supplementary Table 1: References for Outcome measures

Outcome measure	Reference
Barthel	Mahoney FI, Barthel DW. Barthel index. Maryland State Medical Journal. 1965. PMID: 14258950
Challenging Behaviour Scale	Moniz-Cook E, Woods R, Gardiner E, Silver M, Agar S. The Challenging Behaviour Scale (CBS): development of a scale for staff caring for older people in residential and nursing homes. British Journal of Clinical Psychology. 2001 Sep;40(3):309–22. https://doi.org/10.1348/014466501163715
Clinical Dementia Rating	Morris JC. The Clinical Dementia Rating (CDR): current version and scoring rules. Neurology. 1993 Nov. https://doi.org/10.1212/wnl.43.11.2412-a
Clinical Frailty Scale	Rockwood K, Song X, MacKnight C, Bergman H, Hogan DB, McDowell I, Mitnitski A. A global clinical measure of fitness and frailty in elderly people. Cmaj. 2005 Aug 30;173(5):489–95. https://doi.org/10.1503/cmaj.050051
Cohen-Mansfield CMAI	Cohen-Mansfield J. Instruction manual for the Cohen-Mansfield agitation inventory (CMAI). Research Institute of the Hebrew Home of Greater Washington. 1991;1991. https://www.dementiaresearch.org.au/wp-content/uploads/2016/06/CMAI_Manual.pdf
DEMQOL	Smith SC, Lamping DL, Banerjee S, Harwood RH, Foley B, Smith P, Cook JC, Murray J, Prince M, Levin E, Mann A. Development of a new measure of health-related quality of life for people with dementia: DEMQOL. Psychological medicine. 2007 May;37(5):737–46. https://doi.org/10.1017/S0033291706009469
EQ5D-5L	Herdman M, Gudex C, Lloyd A, Janssen MF, Kind P, Parkin D, Bonsel G, Badia X. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). Quality of life research. 2011 Dec;20(10):1727–36. https://doi.org/10.1007/s11136-011-9903-x
EQ5D-3L	Group TE. EuroQol-a new facility for the measurement of health-related quality of life. Health policy. 1990 Dec 1;16(3):199-208. https://doi.org/10.1016/0168-8510(90)90421-9
Minnesota	Talley KM, Wyman JF, Olson-Kellogg BG, Bronas UG, McCarthy TC. Reliability and validity of two measures of toileting skills in frail older women without dementia. Journal of gerontological nursing. 2016 Sep 1;42(9):16–20. https://doi.org/10.3928/00989134-20160531-02
MMSE	Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. Journal of the American Geriatrics Society. 1992 Sep;40(9):922–35. https://doi.org/10.1111/j.1532-5415.1992.tb01992.x
NPI	Cummings JL. The Neuropsychiatric Inventory: assessing psychopathology in dementia patients. Neurology. 1997 May 1;48(5 Suppl 6):10S–6S. https://doi.org/10.1212/wnl.48.5_suppl_6.10s
PAM-RC	Whitney J. *Defining falls risk factors in older adults with cognitive impairment living in residential care* (Doctoral dissertation, King's College London (University of London)). https://doi.org/https://kclpure.kcl.ac.uk/portal/en/studentTheses/defining-falls-risk-factors-in-older-adults-with-cognitive-impair
QUALID	Weiner MF, Martin-Cook K, Svetlik DA, Saine K, Foster B, Fontaine CS. The quality of life in late-stage dementia (QUALID) scale. Journal of the American Medical Directors Association. 2000 May 1;1(3):114–6. PMID: 12818023
QUALIDEM	Ettema TP, Dröes RM, de Lange J, Mellenbergh GJ, Ribbe MW. QUALIDEM: development and evaluation of a dementia specific quality of life instrument—-validation. International Journal of Geriatric Psychiatry: A journal of the psychiatry of late life and allied sciences. 2007 May;22(5):424–30. https://doi.org/10.1002/gps.1713
QOLAD	Logsdon RG, Gibbons LE, McCurry SM, Teri L. Assessing quality of life in older adults with cognitive impairment. Psychosomatic medicine. 2002 May 1;64(3):510-9. https://doi.org/10.1097/00006842-200205000-00016
QOLAD-NH	Edelman P, Fulton BR, Kuhn D, Chang CH. A comparison of three methods of measuring dementia-specific quality of life: perspectives of residents, staff, and observers. The gerontologist. 2005 Oct 1;45(suppl_1):27–36. https://doi.org/10.1093/geront/45.suppl_1.27