iWHELD

CONNECTION, COACHING AND CARE THROUGH COVID AND BEYOND.

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iWHELD: An RCT of A Novel Digital Intervention To Improve Quality of Life and Reduce Psychotropic Medication in Care Home residents with Dementia

Introduction

Huge pressure on Nursing Homes Made worse During COVID

- Staff sickness
- COVID outbreaks
- Limited medical support
- Visiting restrictions

Impact on Staff

- COVID
- Stress and mental health
- Working hours

Impact on Residents

- Health
- Isolation
- Quality of life
- Some suggestion of increased antipsychotic use

Howard et al 2020 Antipsychotic prescribing in COVID DOI: https://doi.org/10.1016/S1474-4422(20)30370-7
https://www.health.org.uk/news-and-comment/charts-and-infographics/deaths-from-any-cause-in-care-homes-have-increased

Risperidone Efficacy: BEHAVE-AD

Ballard & Howard 2006 Nature Neuroscience Reviews

	Target symptom	Mean Difference from placebo	p value	95% CI
Risperidone 1mg	Psychosis	-0.79	p=0.03	-1.31 to -0.27
Risperidone 1mg	Aggression	-0.84	p=0.0002	-1.28 to -0.40
Risperidone 2mg	Aggression	-1.50	p<0.0001	-2.05 to -0.95

Major Adverse Outcomes with antipsychotics over 6-12 weeks (FDA, Schneider et al 2005,Ballard et al 2009)

- Parkinsonism
- Sedation
- Gait disturbance
- Increased respiratory infections
- Oedema
- Accelerated
- cognitive decline (2-4 fold)
- Stroke (>3 fold)
- Other thrombo-embolic events (up to 80%)
- Mortality (1.5-1.7 fold)

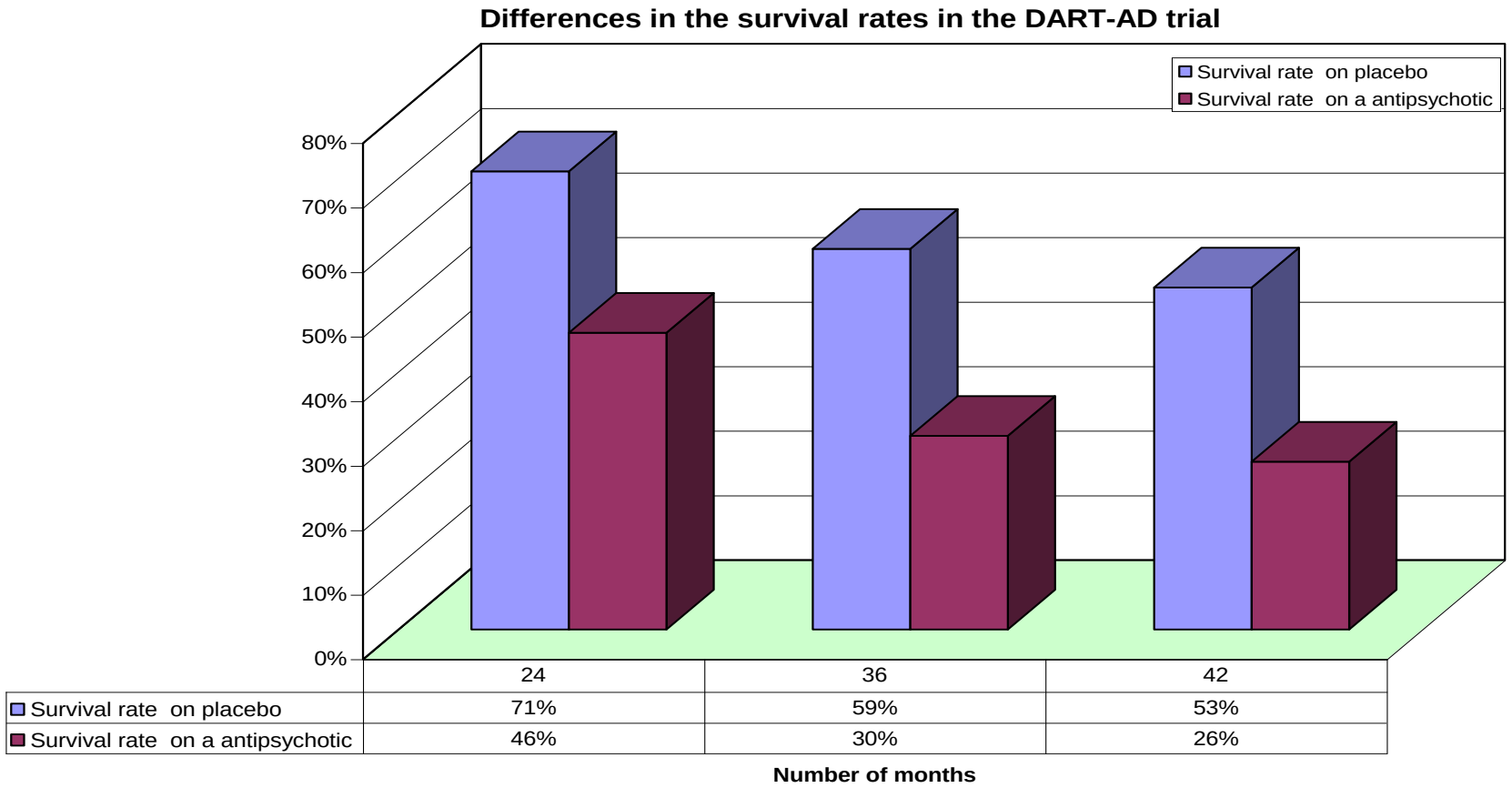
No Benefit and Accelerated Cognitive Decline with Quetiapine

	rivastigmine	quetiapine	placebo	Chl v plac	Nlp v plac
Week 6	N=24 (15 completed SIB)	N=26 (14 completed SIB)	N=29 (17 completed SIB)		
Diff CMAI	-8.3±18.4	-4.7±17.3	-6.2±17.2	T=0.4 P=0.67	T=0.3 P=0.74
Diff SIB	+4.2±15.4	-10.5±14.8	+2.8±15.5	T=0.3 P=0.80	T=2.4 P=0.02*
Week 26	N=24 (16 completed SIB)	N=26 (15 completed SIB)	N=29 (17 completed SIB)		
Diff SIB	-1.1±21.1	-11.6±15.6	+2.3±18.1	T=0.5 P=0.61	T=2.3 P=0.03*
Diff CMAI	-10.5±20.4	-4.4±15.7	-7.9±16.6	T=0.5 P=0.62	T=0.1 P=0.87

AGIT-AD Ballard et al 2005 BMJ

DART AD: Differential Survival

Ballard et al Lancet Neurology 2009



	24	36	42
Survival rate on placebo	71%	59%	53%
Survival rate on a antipsychotic	46%	30%	26%

The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomised placebo-controlled trial. www.thelancet.com/neurology.09 Jan 2009

BMJ

BMJ 2011;343:d4065 doi: 10.1136/bmj.d4065

RESEARCH

Efficacy of treating pain to reduce behavioural disturbances in residents of nursing homes with dementia: cluster randomised clinical trial

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Table 3| **Comparison of Cohen-Mansfield agitation inventory (CMAI) total score between control and intervention (stepwise protocol for treatment of pain) groups using repeated measures analysis of covariance (ANCOVA)***

Week	Mean (SD) CMAI total score		Effect of intervention on CMAI total†		Intracluster correlation coefficient‡
	Control group	Intervention group	Estimate (95% CI)	P value	
0	56.2 (16.1), n=177	56.5 (15.2), n=175	—	—	0.162
2	53.9 (17.0), n=161	52.0 (19.5), n=158	−3.6 (−0.5 to −6.7)	0.022	0.261
4	52.5 (16.3), n=160	49.4 (19.0), n=148	−4.1 (−0.9 to −7.4)	0.012	0.231
8	52.8 (16.8), n=157	46.9 (18.7), n=147	−7.0 (−3.7 to −10.3)	<0.001	0.226
12	52.5 (16.0), n=152	50.3 (20.3), n=142	−3.2 (0.1 to −6.4)	0.058	0.253

*Baseline score as covariate and least squares weighted by number of patients within cluster; P value from multivariate test of intervention was 0.002, and cross effect between week and intervention was <0.001.

†Variable estimate by week of effect of intervention on CMAI score from estimated model.

‡Proportion of total variance between clusters, and measured within framework of ANCOVA.

Clinical Trials of Person Centred Care Interventions in Nursing Homes

Chenoweth, L et.al. 2009 (Australia)	RCT: 15 NH 289 residents 194 care staff	Quality of life Antipsychotics Agitation	CMAI QUALID Falls	Agitation was lower in sites providing DDC and PCC. No change on QOL or antipsychotics
Fossey, J et.al. 2006 (UK)	Rct:12 NH n=349	Quality of life antipsychotics Behavior	CMAI DCM	Significant reduction in antipsychotics. No worsening of behavior No improvement in QOL expect for stopping antipsychotics
Brooker, DJ et.al. 2011 (UK)	Quasi-Experimental design: 10 extra care housing schemes n=293	Quality of life, depression	QOLAD GDS DSSI DCM	Significant decrease in depression after 18 months in the intervention group. No QoL benefit

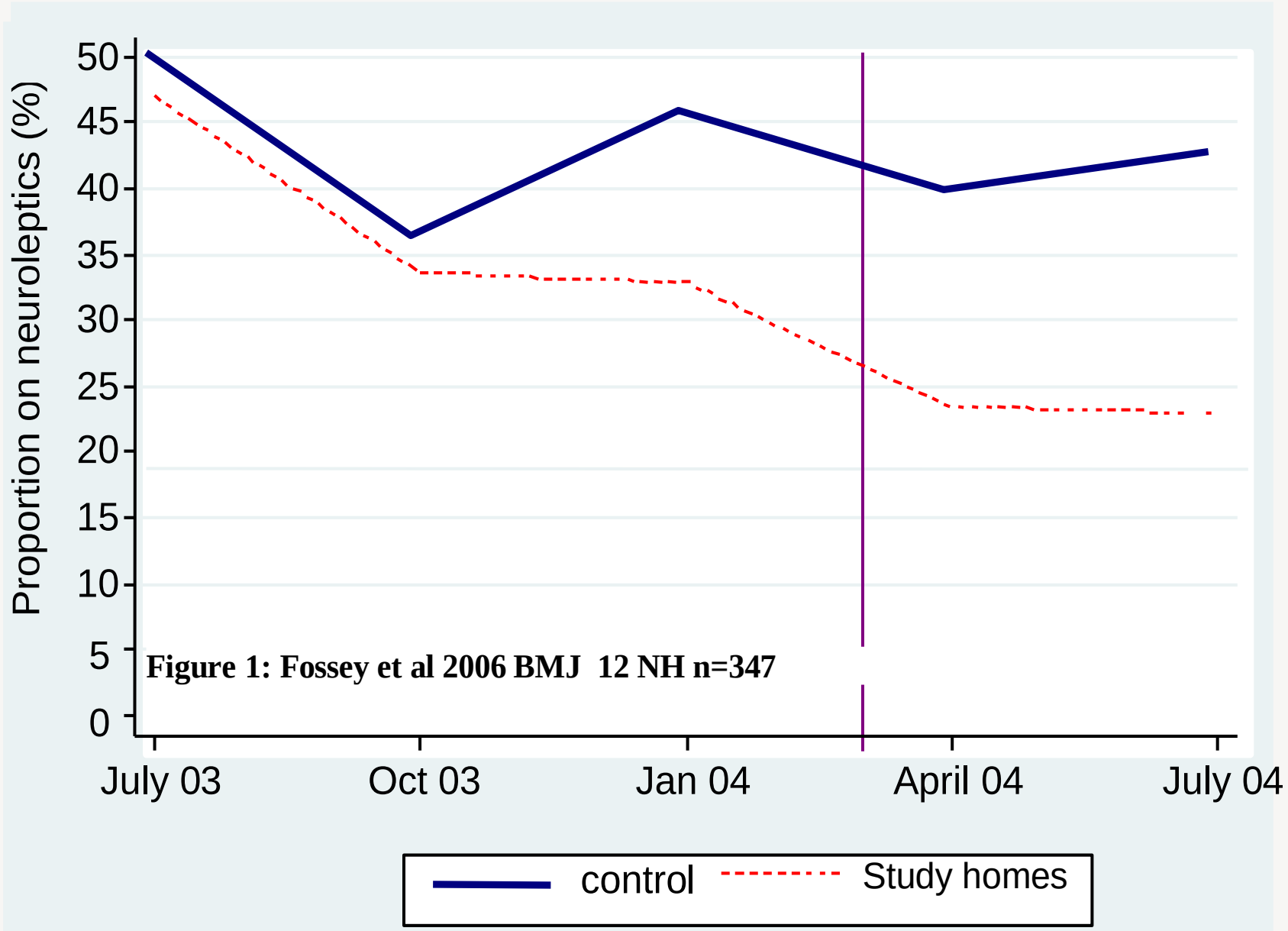


Figure 1: Fossey et al 2006 BMJ 12 NH n=347

WHELD Factorial RCT: Key Results

Ballard et al Am J psychiatry 2016

- AR significantly reduced antipsychotic use by 50% (OR 0.17, 95% CI 0.05 to 0.60, p=0.006).
- AR and SI significantly reduced mortality (OR=0.36, 95% CI 0.23 to 0.57, p<0.001)
- **Benefits in mortality were achieved without a worsening of neuropsychiatric symptoms in people receiving AR and SI (-0.44, CI -4.39 to 3.52, p=0.82)**
- EX significantly improved depression (-4.74, CI 0.76 to 8.72) and neuropsychiatric symptoms (-4.01, 95% CI -7.91 to -0.10, p=0.045).
- SI significantly improved quality of life (6.04, 95% CI 0.24 to 11.84, p=0.042)
- **Combination of both SI and AR (p<0.04) and EX and AR (P<0.02) also significantly improved apathy**

WHELD dementia champion RCT Ballard et al

PLOS Medicine 2018

- 847 residents with dementia in 69 nursing homes
- 9 month cluster RCT
- Key outcomes:
- Quality of Life (DEMQOL proxy)
- Agitation (CMAI)
- Cost

WHELD Parallel group RCT

Ballard et al PLOS Medicine 2018

Outcome measure	Adjusted effect (SE)*	p-Value	Mean difference (SEM)	95% CI of mean difference	Effect size (Cohen's D)	Number needed to treat$^{\Delta}$
DEMQOL-Proxy (n = 553)	R = 0.12 Z = 2.82	0.0042	2.54^{+} (0.88)	0.81, 4.28	0.24	9
CMAI (n = 553)	R = 0.11; Z = 2.68	0.0076	4.27^{+} (1.59)	−7.39, −1.15	0.23	6
NPI-NH (n = 547)	R = −1.5; Z = 3.52	<0.001	4.55^{+} (1.28)	−7.07, −2.02	0.30	9

The quality of interactions of positive care between care staff and residents with dementia (QUIS) was collected as a care-home-level assessment in 62 of the participating care homes. There was a statistically significant 19.7% greater increase in the proportion of positive care interactions from baseline to 9 months in the WHELD group compared to the TAU group (SEM 8.94; 95% CI 2.12, 37.16, p = 0.03; Cohen's D 0.55

WHELD lower cost compared to treatment as usual

social care institute for excellence

KING'S College LONDON

- Partnered with Social Care Institute for Excellence (SCIE) to **develop and evaluate an e-learning training intervention** based on the principles of the WHELD programme

- **Pilot RCT of 160 people with dementia and 50 care staff over 8 months**

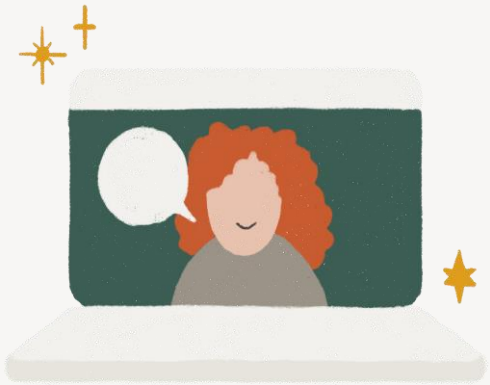
- **significant benefits in wellbeing for people with dementia (23% improvement, p=0.006) and staff attitudes to Person centred care** with a combination of the e-learning intervention and facilitation support compared to e-learning alone

Connection, coaching & care through COVID and beyond

iWHELD

Providing connection, coaching and care through COVID and beyond.

What is iWHELD?



Live virtual group coaching sessions with a trained iWHELD Coach.

An on-demand digital hub filled with ideas, bite-sized videos, and printable resources.

24/7 access to community of peers supported by iWHELD Coaches.

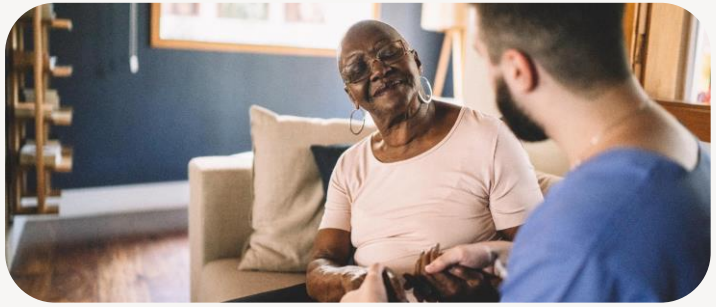
iWHELD is made up of 5 main components:

Person-centred care

Creating moments that matter

Personalised care planning

Understanding unmet needs



Reviewing and reducing medication

Testimonials

Positive participant feedback so far highlights the potential of iWHELD:

“I found this session to be very positive especially discussing issues around those individuals living with dementia who cannot express their needs and wishes very well and who also do not have family to fill in any blanks in knowledge about that individual”.

“I am excited to learn more and use this portal as both a guide and a place to deliver my personal experience/knowledge, to help myself and others in similar positions deliver the best care”.

“Very helpful and good to share ideas for improvement. Felt everyone contributed and gained from call. Lots of ideas to enhance experience in [our] unit”.

Qualitative insights from manager/staff interviews

iWHELD viewed as acceptable (high levels of satisfaction), feasible, a good fit for and useable in the current care home working context. Suits homes with the flexibility to decide what training they need:

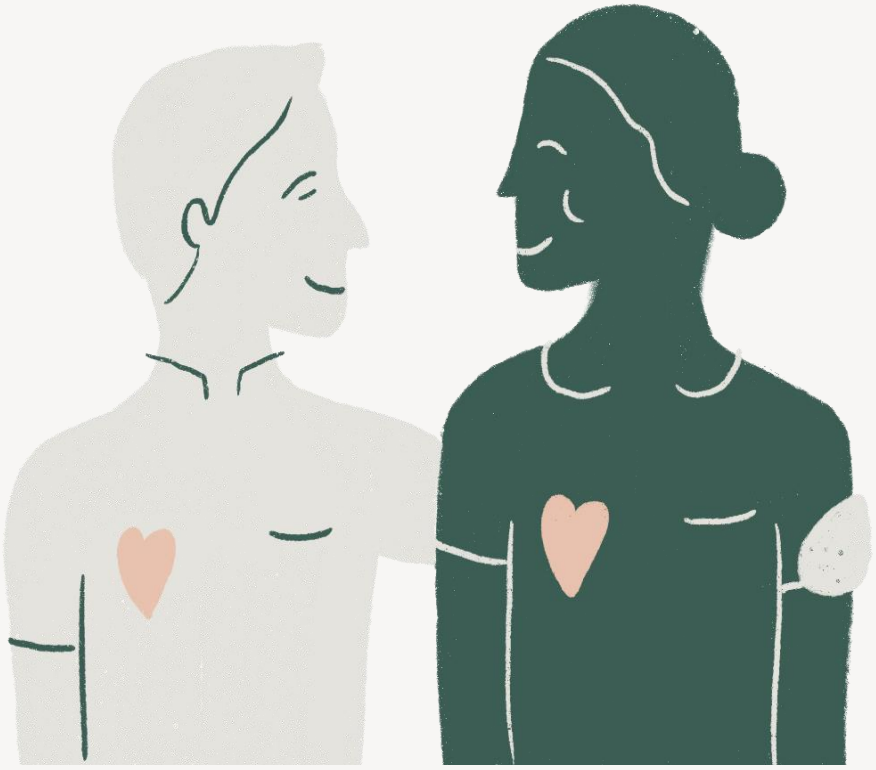
"It was most beneficial getting other people's point of view because I mean some of the things we done and then when you were speaking to other homes and they would say, 'Oh but we do that', and it was like 'Ah we could try that'. We were kind of a bouncing off each other".

"iWHELD is really focussing on that person centred care, it's focussing on practical applications that we can apply to our day-to-day care that we're providing the residents, whereas I found the other online courses a bit more, 'This is dementia', it's just giving the staff information, but it's not giving them practical tools to then go on and put into practice".

"Missions... they relate so easily and directly to the work of the carer or whoever's doing it, I like that because I think it didn't make it seem like all this extra work to do, which I think is exactly right".

"I found that the technical aspects of it have worked really smoothly. Logging into the hub has been straightforward. The hub itself is very intuitive, it's well laid out, very systematic".

Coaching sessions viewed as most beneficial when staff are freed up to attend and when a range of staff from different homes join the call to make sharing experiences more valuable



Design: 16 week, 2 arm parallel Group Single Blind ITT RCT

Sample Characteristics

	iWHELD N=367	TAU n=373	Group Comparison	
Age (Mean/SD)		85.3 (8.45)	t=0.97 p=0.33	
Male	106 (28.9%)	120 (32.3%)	Patient characteristics	COVID iWHELD n=367
Female	260 (70.8%)	252 (67.7%)	Age (Mean - SD)	85.8 (7.55)
Prefer not to say	1 (0.3%)	0 (%)	missing	0

iWHELD Baseline Preliminary Results

- Mean antipsychotic use across the cohort was 32.0% increased from 18% pre-pandemic (Fisher's exact test $p<0.0001$).
- At a Nursing Home level, the medians for the low, medium and high tertiles for antipsychotic use were 7%, 20% and 59% respectively, showing a disproportionate rise in tertile three.
- People with dementia living in these Nursing Homes also showed a small but significant increase in agitation.

Results: Main Analysis

Main Analysis: Intervention n=288, control n=306	F	P Value	Effect Size
Primary outcome/Quality of Life			
EQ5D QOL total change baseline to 16-weeks	6.45	0.01	0.2
DEMQOL-Proxy Overall QOL change baseline to 16-weeks	4.3	0.038	0.12
Secondary outcomes			
Agitation	0.11	0.74	N/A
QOL in People with Agitation (EQ5D) Intervention n=105, control n=139	6.5	0.01	0.34
Psychotropic Drugs	24% v 43% 4.08 Chi Sq	0.044	

Results: Residents with Suspected or Confirmed COVID-19 during Trial

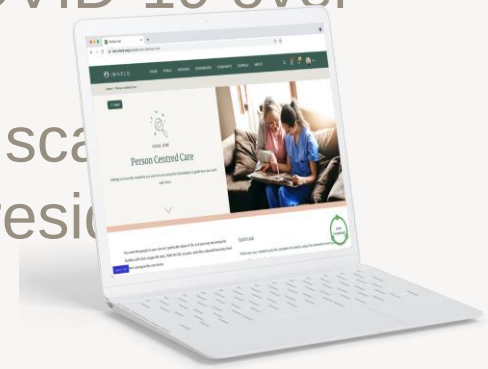
Residents with suspected or confirmed COVID-19 During Trial : Intervention n=86, control n=114	F	P Value	Effect Size
Primary outcome/Quality of Life			
EQ5D QOL total change baseline to 16-weeks	96.7	<0.001	0.37
Secondary outcomes			
Agitation	1.9	0.16	
QOL in People with Agitation (EQ5D) Intervention n=30, Control n=52	7.3	0.009	0.35

Change in QoL on the DEMQOL-Proxy and EQ5D measures in residents at risk of worsening of neuropsychiatric symptoms

Sub-group	f	p-value	Mean difference (SE)	95% CI for mean difference	Cohen's D
Clinically Significant Agitation (NPI C >3)					
DEMQOL-Proxy (overall QoL) (n=207)	4.07	0.06	7.84 (4.19)	-0.42 to 16.09	0.23
EQ5D (n=182)	6.5	0.01	8.67 (3.49)	1.79 -15.56	0.39
Taking Psychotropics					
DEMQOL-Proxy (overall QoL) (n=243)	4.1	0.01	9.38 (3.71)	2.08 to 16.68	0.28
EQ5D (n=216)	6.5	0.02	6.97 (3.05)	0.96 -12.97	0.31

Conclusion

- The iWHELD was successfully delivered and data collected using our iWHELD platform during the COVID-19 pandemic
- iWHELD significantly improved quality of life and reduced the prescription of psychotropic medications without any worsening of neuropsychiatric symptoms
- Benefits in quality of life were larger in people with agitation or taking psychotropic medications at baseline
- The most substantial benefits were seen in people who had COVID-19 over the period of the study
- Beyond COVID-19 this provides an effective, cost-efficient and sca option to improve quality of life an outcomes for nursing home resi dementia



iWHELD could be part of the solution.

With massive thanks to our nursing home partners a and participants for such active engagement in the programme at an extremely challenging