An occupational therapy intervention for residents with stroke related disabilities in UK care homes (OTCH): cluster randomised controlled trial

Catherine M Sackley,[1] Marion F Walker,[2] Christopher R Burton,[3] Caroline L Watkins,[4] Jonathan Mant,[5] Andrea K Roalfe,[6] Keith Wheatley,[7] Bart Sheehan,[8] Leslie Sharp,[9] Katie E Stant,[6] Joanna Fletcher-Smith,[2] Kerry Steel,[10] Kate Wilde,[9] Lisa Irvine,[9] Guy Peryer,[9] on behalf of the OTCH trial investigators

[1]Department of Physiotherapy, King's College London, London, UK
[2]Division of Rehabilitation and Ageing, Faculty of Medicine and Health Sciences, University of Nottingham, Nottingham, UK
[3]School of Healthcare Sciences, Bangor University, Bangor, Gwynedd, UK
[4]School of Health, UCLan, Preston, Lancashire, UK
[5]Primary Care Unit, Department of Public Health & Primary Care, Cambridge, UK
[6]Primary Care Clinical Sciences, University of Birmingham, Birmingham, UK
[7]Cancer Research UK Clinical Trials Unit, University of Birmingham, Birmingham, UK
[8]Directorate of Acute Medicine and Rehabilitation, John Radcliffe Hospital, Oxford, UK
[9]Faculty of Medical and Health Sciences, University of East Anglia, Norwich Research Park, Norwich, NR4 7TJ, UK
[10]Occupational Therapy, Queen Elizabeth Hospital Birmingham, Birmingham, UK
Correspondence to: G Peryer
g.peryer@uea.ac.uk

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STUDY QUESTION

Can an established programme of occupational therapy administered at participant level help maintain functional activity and reduce further health risks caused by inactivity in care home residents living with stroke sequelae?

SUMMARY ANSWER

A three month individualised course of occupational therapy targeting stroke related disabilities had no impact on measures of functional activity, mobility, mood, or health related quality of life, at all observational time points.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Occupational therapy provided to survivors of stroke living at home has shown good evidence of benefit. Providing and targeting ameliorative care for care home residents with stroke related disabilities requires alternative strategies.

Design

A pragmatic, parallel group, cluster randomised controlled trial with economic evaluation. Random allocation of participants occurred at the level of the care home. The treatment arm received standard care plus the intervention—a three month programme of occupational therapy targeting personal activities of daily living (for example, feeding, grooming, dressing, bathing, moving from bed to chair), delivered by qualified occupational therapists and assistants, involving individual assessment, patient centred goal setting, education of care home staff, and appropriate adaptation to the environment. The treatment arm was compared with the control arm which received usual care. Homes were randomised 1:1 to intervention or control. Allocation was masked from the independent assessors but not from treating therapists, residents, and care home managers.

Participants and setting

1042 survivors of stroke resident in one of 228 care homes with more than 10 beds, both with and without the provision of nursing care, and local to 11 trial administrative centres across the United Kingdom. We excluded homes for people with learning disabilities or drug addiction.

Change in Barthel index score (scale 0-20) at three months from baseline

Outcomes	No (%) in intervention group (n=540)	No (%) in control group (n=436)
Poor (decrease in score, or death)	293 (54.3)	227 (52.1)
Moderate (no change in score, or increase of 1 point)	164 (30.4)	150 (34.4)
Good (increase in score ≥2 points)	83 (15.4)	59 (13.5)

Primary outcome

Barthel index of activities of daily living, at the participant level, three months post-randomisation. The measure uses a scale between 0 and 20, with lower scores signifying increased disability.

Main results and the role of chance

All analyses were performed using an intention to treat approach. We observed no clinically important differences between treatment arms in the primary outcome measure at three months. The adjusted mean difference in Barthel index score was 0.19 points higher in the intervention arm (95% confidence interval −0.33 to 0.70, P=0.48). When the change in Barthel index score was compared between baseline and three months, the odds of an improvement were similar between treatment arms (odds ratio 0.96, 95% confidence interval 0.70 to 1.33, P=0.81). The economic analysis suggested that it was unlikely that the trialled intervention is cost effective when compared with usual treatment.

Harms

No adverse events attributable to the intervention were reported.

Bias, confounding, and other reasons for caution

Most participants (>70%) experienced significant cognitive impairment and were graded as severe or very severe on the Barthel index at baseline. This may also have limited participants' capacity to engage in therapy. Overall, 162 out of 1042 participants (11% in each treatment arm) died before the primary outcome.

Generalisability to other populations

The large geographical distribution of the different types of care home, combined with involvement of a high number of qualified therapists and a protocol that did not exclude resident survivors of stroke with cognitive and communication impairments, increase the potential for generalisability of the results to all care homes within the United Kingdom.

Study funding/competing interests

This study was funded by the National Institute for Health Research—Health Technology Assessment programme. All the researchers acted independently of the funder.

Trial registration number

Current Controlled Trials ISRCTN00757750.

Integrated primary care for patients with mental and physical multimorbidity: cluster randomised controlled trial of collaborative care for patients with depression comorbid with diabetes or cardiovascular disease

Peter Coventry,[1] Karina Lovell,[2] Chris Dickens,[3] Peter Bower,[4] Carolyn Chew-Graham,[5] Damien McElvenny,[1] Mark Hann,[6] Andrea Cherrington,[7] Charlotte Garrett,[8] Chris J Gibbons,[9] Clare Baguley,[10] Kate Roughley,[11] Isabel Adeyemi,[1] David Reeves,[4] Waquas Waheed,[12] Linda Gask[8]

EDITORIAL by Gunn

[1]NIHR Collaboration for Leadership in Applied Health Research Greater Manchester and Care and Manchester Academic Health Science Centre, University of Manchester, Manchester M13 9PL, UK
[2]School of Nursing, Midwifery and Social Work and Manchester Academic Health Science Centre, University of Manchester, Manchester M13 9PL, UK
[3]Institute of Health Service Research, University of Exeter Medical School, Exeter EX1 2LU, UK
[4]NIHR School for Primary Care Research and Manchester Academic Health Science Centre, University of Manchester, Manchester M13 9PL, UK
[5]Research Institute, Primary Care and Health Sciences and NIHR Collaboration for Leadership in Applied Health Research and Care West Midlands, University of Keele, Keele ST5 5BG, UK
[6]Centre for Biostatistics and Manchester Academic Health Science Centre, University of Manchester, Manchester M13 9PL, UK
[7]Research Institute, Primary Care and Health Sciences, University of Keele, Keele ST5 5BG, UK
[8]Centre for Primary Care and Manchester Academic Health Science Centre, University of Manchester, Manchester M13 9PL, UK
[9]Manchester Centre for Health Psychology, University of Manchester, Manchester M13 9PL, UK
[10]NHS Health Education North West, Manchester M1 3BN, UK
[11]Division of Clinical Psychology, University of Liverpool, Liverpool L69 3GB, UK
[12]Lancashire Care NHS Foundation Trust, Preston PR5 6AW, UK
Correspondence to: P Coventry **peter.a.coventry@manchester.ac.uk**

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STUDY QUESTION

Is integrated collaborative care more effective than usual care for managing depression in people with multimorbidity?

SUMMARY ANSWER

Collaborative care that integrated depression care in primary care was more effective in reducing severity of depression in patients with high levels of mental and physical multimorbidity.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

There is evidence that the benefits of collaborative care can translate to settings outside the United States, but there is uncertainty if these benefits are realisable in more routine settings and among patients with multimorbidity. The COINCIDE trial is a pragmatic demonstration of how depression care can effectively be integrated within routine chronic disease management with only minimal changes to the organisation of primary care and with clinical benefits to patients with multimorbidity.

Design

General practices were randomised as they were recruited by using a central randomisation service. Allocation of practices (other than the first six, which were allocated 1:1 at random) was by minimisation based on deprivation and list size of each practice. Patients with diabetes and/or heart disease were identified from practice disease registers and screened for depression. Clinical staff with responsibilities for treating patients and research staff who undertook baseline and follow-up assessments were masked to allocations. Patients received either integrated collaborative care or usual care. Collaborative care included up to eight sessions of guided self help based on cognitive and behavioural therapy delivered by a psychological wellbeing practitioner; up to two sessions were held jointly with the practice nurse.

Participants and setting

A total of 387 primary care patients with depression and diabetes and/or heart disease and a mean of 6.2 (SD 3.0) other long term physical conditions were identified from 36 general practices in the English NHS.

Primary outcome

Reduction in depression severity at four months.

Main results and the role of chance

Intention to treat analyses found that the mean depression score on the primary outcome (symptom checklist depression scale) was 0.23 points lower (95% confidence interval −0.41 to −0.05; P=0.014) in participants who received collaborative care compared with those who received usual care. The size of the observed treatment effect is equivalent to a standardised mean difference of 0.30 (−0.54 to −0.07). We also found a significant difference between the groups for anxiety symptoms, self management, patient centredness, and patient satisfaction.

Harms Four deaths unrelated to delivery of the intervention occurred during the study.

Bias, confounding, and other reasons for caution

The main areas of uncertainty were missing data and differential follow-up. Complete case analyses returned the same pattern of results for the primary outcome (−0.24, 95% confidence interval −0.38 to −0.11; P=0.001).

Generalisability to other populations

This was a pragmatic trial run in routine primary care and used existing providers to deliver interventions. Additionally, the population recruited had high levels of mental and physical multimorbidity. Integrated collaborative care is therefore likely to have clinical utility for a wide range of patients with depression and/or anxiety and multiple long term physical health conditions.

Study funding/potential competing interests This study was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care Greater Manchester. None of the authors has competing interests to declare.

Secondary outcomes with clinical utility for collaborative care in patients with depression and multimorbidity

	Intervention		Control		Comparison	
Outcome	No of patients	Mean (SD) score	No of patients	Mean (SD) score	Difference in means (95% CI)	Standardised mean difference
Anxiety	157	8.2 (5.8)	168	9.7 (5.9)	−1.45 (−2.45 to −0.56)	−0.28
Self monitoring	155	3.65 (0.7)	165	3.32 (1.0)	0.31 (0.01 to 0.52)	0.36
Patient centredness	155	2.37 (1.1)	163	1.98 (1.0)	0.39 (0.16 to 0.62)	0.37
Patient satisfaction	156	2.90 (0.6)	160	2.58 (0.6)	0.32 (0.19 to 0.45)	0.53

Antidepressant use and risk of suicide and attempted suicide or self harm in people aged 20 to 64: cohort study using a primary care database

Carol Coupland,[1] Trevor Hill,[1] Richard Morriss,[2] Antony Arthur,[3] Michael Moore,[4] Julia Hippisley-Cox[1]

EDITORIALS by Sinyor and Cheung

[1]Division of Primary Care, School of Medicine, University of Nottingham, University Park, Nottingham NG7 2RD, UK
[2]Institute of Mental Health, Jubilee Campus, Nottingham, UK
[3]School of Nursing Sciences, Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, UK
[4]University of Southampton Medical School, Primary Care and Population Sciences, Aldermoor Health Centre, Southampton, UK
Correspondence to: C Coupland
carol.coupland@nottingham.ac.uk

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STUDY QUESTION

To what extent do rates of suicide and attempted suicide or self harm vary in patients treated with different antidepressants?

SUMMARY ANSWER

Rates of suicide and attempted suicide or self harm were similar during periods of treatment with selective serotonin reuptake inhibitors (SSRIs) and tricyclic and related antidepressants (TCAs) overall, but were higher with other antidepressants and in the first 28 days after starting or stopping treatment.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

Rates of suicide and attempted suicide are increased in people with depression but to what extent they vary for different antidepressants is unclear. In this study, rates of suicide and attempted suicide or self harm were similar during periods of treatment with SSRIs and TCAs; other antidepressants were associated with the highest rates, although this may reflect indication biases and residual confounding.

Participants and setting

Adults aged 20-64 with a first diagnosis of depression between 1 January 2000 and 31 July 2011, followed up until 1 August 2012 and registered with general practices contributing data to the QResearch database.

Design, size, and duration

Cohort study of 238 963 patients with depression, with a median follow-up of 5.2 years. We calculated hazard ratios for suicide and attempted suicide or self harm during follow-up according to antidepressant class, dose, and duration of treatment, and for commonly prescribed antidepressants.

Main results and the role of chance

The difference in suicide rates of patients using TCAs compared with SSRIs was not significant, but the suicide rate was significantly increased during periods of treatment with other antidepressants. The adjusted hazard ratio for suicide was significantly increased for mirtazapine compared with citalopram. Absolute risks of suicide over one year ranged from 0.02% for amitriptyline to 0.19% for mirtazapine. There was no significant difference in the rate of attempted suicide or self harm with TCAs compared with SSRIs, but the rate was significantly higher for other antidepressants. Adjusted hazard ratios for attempted suicide or self harm were significantly increased for three of the most commonly prescribed drugs compared with citalopram: venlafaxine, trazodone, and mirtazapine, and significantly reduced for amitriptyline. Absolute risks of attempted suicide or self harm over one year ranged from 1.02% for amitriptyline to 2.96% for venlafaxine. Rates were highest in the first 28 days after starting treatment and remained increased in the first 28 days after stopping.

Adjusted hazard ratios for suicide and attempted suicide or self harm by antidepressant class and individual drug over five year follow-up period

Antidepressants	Adjusted hazard ratio* (95% CI)	
	Suicide	Attempted suicide or self harm
Antidepressant class		
SSRIs	1.00	1.00
TCAs	0.84 (0.47 to 1.50)	0.96 (0.87 to 1.08)
Other antidepressants	2.64 (1.74 to 3.99)	1.80 (1.61 to 2.00)
Combined antidepressants	1.36 (0.32 to 5.68)	2.00 (1.54 to 2.59)
No current use	0.39 (0.28 to 0.55)	0.36 (0.34 to 0.39)
Antidepressant drugs		
SSRIs:		
Citalopram	1.00	1.00
Escitalopram	0.89 (0.31 to 2.55)	1.05 (0.87 to 1.26)
Fluoxetine	1.03 (0.60 to 1.79)	0.92 (0.84 to 1.02)
Paroxetine	1.59 (0.77 to 3.28)	0.91 (0.78 to 1.06)
Sertraline	1.15 (0.51 to 2.63)	1.07 (0.92 to 1.23)
TCAs:		
Amitriptyline	0.68 (0.24 to 1.96)	0.71 (0.59 to 0.85)
Dosulepin	1.04 (0.40 to 2.74)	1.04 (0.86 to 1.26)
Lofepramine	1.06 (0.25 to 4.60)	1.08 (0.84 to 1.38)
Trazodone	2.00 (0.47 to 8.57)	1.73 (1.26 to 2.37)
Others:		
Mirtazapine	3.70 (2.00 to 6.84)	1.70 (1.44 to 2.02)
Venlafaxine	2.23 (1.14 to 4.39)	1.85 (1.61 to 2.13)
All other antidepressants	1.15 (0.28 to 4.76)	1.05 (0.80 to 1.39)
Combined antidepressants	1.45 (0.33 to 6.43)	1.94 (1.50 to 2.52)

SSRIs=selective serotonin reuptake inhibitors; TCAs=tricyclic and related antidepressants.
*Adjusted for age, sex, year of diagnosis of depression, severity of depression, deprivation, smoking status, alcohol intake, ethnic group, comorbidities, use of other drugs. Suicide outcome also adjusted for attempted suicide or self harm at baseline. For full details see tables 2 and 3 on thebmj.com.

Bias, confounding, and other reasons for caution

As this is an observational study the results may reflect indication biases and residual confounding from severity of depression and differing characteristics of patients prescribed different antidepressants. The number of suicide events was small leading to imprecise estimates.

Generalisability to other populations

The findings are generalisable to the UK population aged 20-64 with a first diagnosis of depression in primary care.

Study funding/potential competing interests

This project was funded by the National Institute for Health Research (NIHR) School for Primary Care Research (project No 81). JH-C is director of QResearch, a not for profit venture between the University of Nottingham and Egton Medical Information Systems (supplier of general practice clinical systems).

Differentiation between traumatic tap and aneurysmal subarachnoid hemorrhage: prospective cohort study

Jeffrey J Perry,[1] Bader Alyahya,[1] Marco L A Sivilotti,[2] Michael J Bullard,[3] Marcel Émond,[4] Jane Sutherland,[5] Andrew Worster,[6] Corinne Hohl,[7] Jacques S Lee,[8] Mary A Eisenhauer,[9] Merril Pauls,[10] Howard Lesiuk,[11] George A Wells,[12] Ian G Stiell[1]

[1]Department of Emergency Medicine, University of Ottawa, Ottawa Hospital Research Institute, Ottawa Hospital 1053 Carling Avenue Room F647, Ottawa, ON, Canada, K1Y 4E9
[2]University of Ottawa, Department of Emergency Medicine, Ottawa, ON, Canada
[3]Department of Emergency Medicine, University of Alberta, Edmonton, AB, Canada
[4]Hopital de l'Enfant-Jesus, Department of Emergency Medicine, Faculty of Medicine, Quebec City, QC, Canada G1J 1Z4
[5]Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, ON, Canada
[6]Department of Emergency Medicine, McMaster University, Hamilton, ON, Canada
[7]Department of Emergency Medicine, University of British Columbia, Vancouver, BC, Canada
[8]Division of Emergency Medicine, University of Toronto, Toronto, ON, Canada
[9]Division of Emergency Medicine, University of Western Ontario, London, ON, Canada
[10]Department of Emergency Medicine, University of Manitoba, Winnipeg, MB, Canada
[11]Division of Neurosurgery, University of Ottawa, Ottawa, ON, Canada
[12]Department of Epidemiology and Community Medicine, University of Ottawa, Ottawa Hospital Research Institute, Ottawa, ON, Canada
Correspondence to: J J Perry, Clinical Epidemiology Unit, F647, Ottawa Hospital, 1053, Carling Avenue, Ottawa, ON, Canada K1Y 4E9 **jperry@ohri.ca**

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SUMMARY QUESTION

What are the findings in cerebrospinal fluid of patients with acute headache that could distinguish a subarachnoid hemorrhage from a traumatic lumbar puncture?

SUMMARY ANSWER

No xanthochromia and red blood cell count <2000×10^6/L reasonably exclude the diagnosis of aneurysmal subarachnoid hemorrhage.

WHAT IS KNOWN AND WHAT THIS PAPER ADDS

It is often difficult to differentiate blood seen in cerebrospinal fluid as a result of true subarachnoid hemorrhage rather than from a traumatic tap. This study found that a red blood cell count of less than 2000×10^6/L and no xanthochromia reasonably rules out an aneurysmal subarachnoid hemorrhage. Most patients with acute headache meeting this cut off will need no further investigations, and aneurysmal subarachnoid hemorrhage can be excluded as a cause of their headache.

Participants and setting

Alert patients aged over 15 with an acute non-traumatic headache who underwent lumbar puncture to rule out subarachnoid hemorrhage in 12 Canadian academic emergency departments.

Design, size, and duration

This was a planned substudy from a prospective multicenter cohort study, designed to derive and validate the Ottawa SAH (subarachnoid hemorrhage) rule. It was conducted between November 2000 and December 2009. Study sites had a mean of 52 000 visits annually and a mean of 445 inpatient beds. During our study period 4131 patients were enrolled in the Ottawa SAH rule study, of those 1739 (42.1%) patients underwent lumbar puncture and were included in this substudy.

Classification performance of threshold used to diagnose subarachnoid hemorrhage in patients with acute headache and abnormal lumbar puncture results

	Positive for subarachnoid hemorrhage (n=15)	Negative for subarachnoid hemorrhage (n=626)
Classification:		
High risk	15	55
Low risk*	0	571
Sensitivity % (95% CI)	100.0 (74.7 to 100)	
Specificity % (95% CI)	91.2 (88.6 to 93.3)	
Positive likelihood ratio % (95% CI)	11.4 (8.8 to 14.6)	
Negative likelihood ratio % (95% CI)	0 (NA)†	
Positive predictive value % (95% CI)	21.4 (12.9 to 33.2)	
Negative predictive value % (95% CI)	100.0 (99.2 to 100.0)	

* Red blood cells <2000x10^6/L, no xanthochromia
† NA=not applicable (confidence interval undefined)

Main results and the role of chance

During this substudy we enrolled 1739 patients, of whom 641 (36.9%) had abnormal results on cerebrospinal fluid analysis, with >1×10^6/L red blood cells in the final tube of cerebrospinal fluid or xanthochromia in one or more tubes. There were 146 cases of aneurysmal subarachnoid hemorrhage in the larger cohort (n=4131), including 15 (10.3%) patients in this substudy who had abnormal results on lumbar puncture. The presence of less than 2000×10^6/L red blood cells in addition to no xanthochromia excluded the diagnosis of aneurysmal subarachnoid hemorrhage with a sensitivity of 100% (95% confidence interval 74.7% to 100%) and a specificity of 91.2% (88.6% to 93.3%).

Bias, confounding, and other reasons for caution

The main limitation of this study is the relatively wide confidence interval around the sensitivity. This is because of the low number of cases, despite a 10 year study period at many sites. This relates to most cases of subarachnoid hemorrhage being diagnosed by computed tomography. Given these results, patients with a high pretest probability of subarachnoid hemorrhage and an abnormal result on lumbar puncture in the "low risk" category might need further investigations.

Generalizability to other populations

These results are generalizable to adults undergoing investigations for possible subarachnoid hemorrhage. Most patients with a "low risk" result on lumbar puncture should be considered as not having a subarachnoid hemorrhage.

Study funding/potential competing interests

This study was funded by the Canadian Institutes of Health Research, the Ontario Ministry of Health and Long Term Care, and the physicians of Ontario through the Physician's Services Incorporated Foundation.