**Participant Flow**

**Study A – people with dementia**

**EXCLUDED (N= 232)**

* Not meeting inclusion criteria (n=120)
* Declined to participate (n=18)
* Other reasons (n=92)
* Did not consent (2)

**ASSESSED FOR ELIGIBILITY (n=282)**

## Enrollment

## Allocation

## Analysis

**TOOK PART IN THE STUDY (N=50)**

**ANALYSED (N= 50)**

* Excluded from analysis (n=0 )

**Site information**

* Recruitment period:Feb 2015 – Oct 2015
* Incorporating one memory clinic
* One researcher

**Study A – Healthy Volunteer controls**

**EXCLUDED (N= 54)**

* **Not meeting inclusion criteria (n=1)**
  + Site 1 = 1
* **Declined to participate/did not respond to info sheet (n=14)**
  + Site 1 = 10
  + Site 2 = 4
  + Site 3 = 0
* **Other reasons (n=39)**
  + Site 1 = 27
  + Site 2 = 7
  + Site 3 = 5

**ASSESSED FOR ELIGIBILITY/ INITIALLY INTERESTED IN TAKING PART (n= 110)**

* Site 1 = 59
* Site 2 = 36
* Site 3 = 15

## Enrollment

## Allocation

## Analysis

**TOOK PART IN THE STUDY (N=56)**

* Site 1 = 20
* Site 2 = 26
* Site 3 = 10

**ANALYSED (N= 52)**

* Site 1 = 19
* Site 2 = 23
* Site 3 = 10

**EXCLUDED FROM ANALYSIS (N=0)**

* Site 1 = 1
* Site 2 = 3
* Site 3 = 0

**Control 1 (JDR)**

* Recruitment period: March 2016 – June 2016
* one researcher

**Control 2 (Staff and family)**

* Recruitment period: May 2016 – July 2016
* Three researchers

**Control 3 (Students)**

* Recruitment period: January 2016 – May 2016
* One researcher

No missing/partial data in the control condition

Excluded data:

* 1 participant from site one due to low cognitive score
* 3 participants from site two due to high anxiety and/or depression scores.

**Study B – people with dementia**

**EXCLUDED (N= 232)**

* Not meeting inclusion criteria (n=120)
* Declined to participate (n=18)
* Other reasons (n=92)
* Did not consent (2)

**ASSESSED FOR ELIGIBILITY (n=282)**

## Enrollment

**ALLOCATED TO INTERVENTION ‘SELF’ (N=25)**

* Received allocated intervention (n=25)
* Did not receive allocated intervention (n=0)

**ALLOCATED TO INTERVENTION ‘CHRIS’ (N= 25)**

* Received allocated intervention (n=25 )
* Did not receive allocated intervention (n=0)

## Allocation

**RANDOMISED (N=50)**

**ANALYSED (N= 25)**

* Excluded from analysis (n=0 )

**ANALYSED (N=25)**

* Excluded from analysis (n=0)

## Analysis

**Site information**

* **Recruitment period: Feb 2015 – Oct 2015**
* **Incorporating one memory clinic**
* **One researcher**

**Study B – Healthy Volunteer controls**

**ASSESSED FOR ELIGIBILITY/ INITIALLY INTERESTED IN TAKING PART (n= 110)**

* Site 1 = 59
* Site 2 = 36
* Site 3 = 15

## Enrollment

**EXCLUDED (N= 54)**

* **Not meeting inclusion criteria (n=1)**
  + Site 1 = 1
* **Declined to participate/did not respond to info sheet (n=14)**
  + Site 1 = 10
  + Site 2 = 4
  + Site 3 = 0
* **Other reasons (n=39)**
  + Site 1 = 27
  + Site 2 = 7
  + Site 3 = 5

**ALLOCATED TO INTERVENTION ‘SELF’ (N=28)**

* **Received allocated intervention (n=28)**
  + Site 1 = 10
  + Site 2 = 12
  + Site 3 = 6
* **Did not receive allocated intervention (n=0)**

**ALLOCATED TO INTERVENTION ‘CHRIS’ (N= 28)**

* **Received allocated intervention (n=28)**
  + Site 1 = 10
  + Site 2 = 14
  + Site 3 = 4
* **Did not receive allocated intervention (n= 0)**

## Allocation

**RANDOMISED (N=56)**

* Site 1 = 20
* Site 2 = 26
* Site 3 = 10

**ANALYSED (n=27)**

* Site 1 = 10
* Site 2 = 11
* Site 3 = 6
* **Excluded from analysis (n=1)**
* Site 1 = 0
* Site 2 = 1
* Site 3 = 0

## Analysis

**ANALYSED (n= 25)**

* Site 1 = 9
* Site 2 = 12
* Site 3 = 4
* **Excluded from analysis (n=3)**
* Site 1 = 1
* Site 2 = 2
* Site 3 = 0

**NOTES:**

**Control 1 (JDR)**

* Recruitment period: March 2016 – June 2016
* one researcher

**Control 2 (Staff and family)**

* Recruitment period: May 2016 – July 2016
* Three researchers

**Control 3 (Students)**

* Recruitment period: January 2016 – May 2016
* One researcher

No missing/partial data in the control condition

Excluded data:

* 1 participant in the ‘Self’ condition from site two due to high anxiety and/or depression scores.
* 2 participants in the ‘Chris’ condition from site two due to high anxiety and/or depression scores.
* 1 participant in the ‘Chris’ condition from site one due to low cognitive score

**Study C – people with dementia**

**ASSESSED FOR ELIGIBILITY (n= 1708)**

* Site 1 = 1362
* Site 2 = 255
* Site 3 = 91

**EXCLUDED (n=1638)**

* **Not meeting inclusion criteria (n=1459)**
  + Site 1 = 1216
  + Site 2 = 224
  + Site 3 = 19
* **Declined to participate (n=71)**
  + Site 1 = 49
  + Site 2 = 12
  + Site 3 = 10
* **Other reasons (n=108)**
  + Site 1 = 57
  + Site 2 = 8
  + Site 3 = 43

## Enrollment

**RANDOMIZED (n= 70)**

* Site 1 = 40
* Site 2 = 11
* Site 3 = 19

## Allocation

**ALLOCATED TO INTERVENTION ‘SELF’ (n=35)**

* **Received allocated intervention (n=35)**
  + Site 1 = 21
  + Site 2 = 5
  + Site 3 = 9
* **Didn’t receive allocated intervention (n=0)**

**ALLOCATED TO INTERVENTION ‘CHRIS’ (n=35)**

* **Received allocated intervention (n=34)**
  + Site 1 = 19
  + Site 2 = 6
  + Site 3 = 10
* **Didn’t receive allocated intervention (n=1)**
  + Site 1 = 1

## Analysis

**ANALYSED (n=31)**

* Site 1 = 16
* Site 2 = 5
* Site 3 = 10
* **Excluded from analysis (n=3)**
* Site 1 = 2
* Site 2 = 1
* Site 3 = 0

**ANALYSED (n=31)**

* Site 1 = 18
* Site 2 = 4
* Site 3 = 9
* **Excluded from analysis (n=4)**
* Site 1 = 3
* Site 2 = 1
* Site 3 =0

**NOTES:**

**Site 1**

* Recruitment period: Feb 2015 – Dec 2015
* Incorporating five memory clinics
* one researcher

**Site 2**

* Recruitment period: July 2015 – Dec 2015
* Incorporating three assessment teams
* Three researchers

**Site 3**

* Recruitment period: Oct 2015 – Dec 2015
* Incorporating one memory clinic
* One researcher

1 participant in the ‘Chris’ condition did not receive the intervention from site one because they withrew their consent to take part

Missing/partial data still included in the analysis:

* 3 participants in the Chris condition for site one
* 1 participant in the Chris condition for site two

Excluded data:

* 4 participants in the self condition:
  + 2 participants excluded due to high anxiety and depression scores – site one
  + 1 participant excluded due to high anxiety and depression scores – site two
  + 1 participant excluded due to being randomised to ‘Chris’ but researcher documented as allocated to ‘Self’. Unable to confidently say which condition they were in so decided to exclude from analysis – site one
* 3 participants in the Chris condition:
  + 1 participant excluded due to high anxiety and depression scores – site one
  + 1 participant excluded due to missing recall data – site one
  + 1 participant excluded due to missing recall data – site two

**Study C – Healthy Volunteer controls**

**ASSESSED FOR ELIGIBILITY/ / INITIALLY INTERESTED IN TAKING PART (n= 110)**

* Site 1 = 59
* Site 2 = 36
* Site 3 = 15

## Enrollment

**EXCLUDED (N= 54)**

* **Not meeting inclusion criteria (n=1)**
  + Site 1 = 1
* **Declined to participate/did not respond to info sheet (n=14)**
  + Site 1 = 10
  + Site 2 = 4
  + Site 3 = 0
* **Other reasons (n=39)**
  + Site 1 = 27
  + Site 2 = 7
  + Site 3 = 5

**ALLOCATED TO INTERVENTION ‘SELF’ (N=29)**

* **Received allocated intervention (n=28)**
  + Site 1 = 10
  + Site 2 = 14
  + Site 3 = 5
* **Did not receive allocated intervention (n=1)**
  + Site 1 = 1

**ALLOCATED TO INTERVENTION ‘CHRIS’ (N= 27)**

* **Received allocated intervention (n=28)**
  + Site 1 = 11
  + Site 2 = 12
  + Site 3 = 5
* **Did not receive allocated intervention (n= 0)**

## Allocation

**RANDOMISED (N=56)**

* Site 1 = 20
* Site 2 = 26
* Site 3 = 10

**ANALYSED (n=27)**

* Site 1 = 9
* Site 2 = 13
* Site 3 = 5
* **Excluded from analysis (n=1)**
* Site 1 = 0
* Site 2 = 1
* Site 3 = 0

## Analysis

**ANALYSED (n= 25)**

* Site 1 = 10
* Site 2 = 10
* Site 3 = 5
* **Excluded from analysis (n=3)**
* Site 1 = 1
* Site 2 = 2
* Site 3 = 0

**NOTES:**

**Control 1 (JDR)**

* Recruitment period: March 2016 – June 2016
* one researcher

**Control 2 (Staff)**

* Recruitment period: May 2016 – July 2016
* Three researchers

**Control 3 (Students)**

* Recruitment period: January 2016 – May 2016
* One researcher

1 participant from site one was randomised to the ‘Self’ condition but was administered to the ‘Chris’ condition. This was identified before data analysis and it was clear from the CRFs that they took part in the Chris condition so were analysed as such.

No missing/partial data in the control condition

Excluded data:

* 1 participant in the ‘Self’ condition from site two due to high anxiety and/or depression scores.
* 2 participants in the ‘Chris’ condition from site two due to high anxiety and/or depression scores.
* 1 participant in the ‘Chris’ condition from site one due to low cognitive score

**Baseline Characteristics**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Study A and B, Dementia arm**  **(n = 50)** | **Study C, dementia arm**  **(n=62)** | **Study A, B and C, control arm**  **(n = 52)** |
| **Gender (male/female)** | 24/26 | 30/32 | 13/39 |
| **Diagnosis (Alzheimer’s disease/vascular/mixed)** | 29/11/10 | 41/12/9 | NA |
| **Mean Age (SD)** | 81.08 (7.23) | 80.13 (7.40) | 48.18 (18.26) |
| **Cognitive level - Mean score on MoCA (SD)** | 17.76 (2.71) | 19.45 (2.65) | 28.1 (1.25) |
| **Anxiety - mean score on GAI (SD)** | 1.16 (1.60) | 2.42 (3.35) | 2.56 (2.97) |
| **Depression - mean score on GDS (SD)** | 2.06 (1.46) | 2.50 (1.04) | 1.21 (1.30) |

**Outcome measures**

**Study A**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Dementia participants (n=50)** | | **Control participants (n=52)** | |
|  | **Dementia words** | **Neutral words** | **Dementia** | **Control** |
| **Mean aggregate recall** | 8.22  (2.289) | 7.82  (2.654) | 12.88  (2.518) | 13.92  (3.217) |

**Study B**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | **Centrality** | **Self** | | **Chris** | |
| **Positive** | **Negative** | **Positive** | **Negative** |
| **Mean recall accuracy** | **Dementia** | **Central** | 1.720 (0.980) n=25 | 2.480 (1.229) n=25 | 1.333 (0.963) n=25 | 2.500 (1.142) n=25 |
| **Peripheral** | 0.680 (0.627) n=25 | 0.680 (1.030) n=25 | 0.792 (0.658) n=25 | 0.708 (0.550) n=25 |
| **Control** | **Central** | 3.185 (0.962) n=27 | 4.667 (1.358) n=27 | 3.280 (1.137) n=25 | 3.960 (0.978) n=25 |
| **Peripheral** | 1.630 (1.334) n=27 | 1.667 (01.000) n=27 | 1.720 (0.936) n=25 | 2.040 (1.338) n=25 |
| **Mean discrimination index (*d*1)****recognition scores** | **Dementia** | **Central** | 0.543 (0.149) n=25 | 0.110 (0.253) n=25 | 0.448 (0.246) n=25 | 0.521 (0.278) n=25 |
| **Peripheral** | 0.403 (0.246) n=25 | 0.110 (0.200) n=25 | 0.309 (0.269) n=25 | 0.080 (0.239) n=25 |
| **Control** | **Central** | 0.702 (0.153) n=27 | 0.653 (0.224) n=27 | 0.698 (0.131) n=25 | 0.572 (0.241) n=25 |
| **Peripheral** | 0.721 (0.187) n=27 | 0.560 (0.247) n=27 | 0.638 (0.194) n=25 | 0.498 (0.215) n=25 |

**Study C**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Dementia participants (n=62)** | | **Control participants (n=52)** | |
|  | **Self (n=31)** | **Other (n=31)** | **Self (n=26)** | **Other (n=26)** |
| Mean recall - least threatening | 1.742 (1.505) | 1.516 (1.288) | 5.959 (2.093) | 5.400 (1.915) |
| Mean recall - most threatening | 2.419 (1.432) | 3.258 (1.527) | 5.889 (2.118) | 6.040 (1.670) |
| Total protective intrusive error | 11 | 7 | 9 | 2 |
| Total threatening intrusive error | 4 | 14 | 19 | 13 |
| Mean discrimination index scores (*d*1) for recognition - least threatening | 0.167 (0.12) | 0.204 (0.25) | 0.608 (0.25) | 0.585 (0.22) |
| Mean discrimination index scores (*d*1) for recognition - most threatening | 0.178 (0.18) | 0.188 (0.18) | 0.608 (0.25) | 0.644 (0.24) |

**Adverse events**

There were no reported adverse events associated with this trial.