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Using therapeutic touch to restore energy imbalances and manage difficult behaviours in patients with dementia

Submission date
09/01/2017

Recruitment status
No longer recruiting

Registration date
19/01/2017

Overall study status
Completed

Last Edited
13/07/2022

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Dementia is a common condition that causes a decline in memory. Dementia can reduce someone's ability to perform their normal daily activities, causing discomfort, anxiety, restlessness, and wandering. The risk of dementia increases with age, with most cases reported in patients over 65. Therapeutic Touch (TT) is a type of alternative therapy based on the belief that a person and his/her illness are reflected in an imbalance of their energy field. Imbalances are restored using a technique in which a therapist uses their hands to direct human energy for healing purposes. TT is becoming more popular due to its role in improving symptoms such as pain, sleep disturbances, depression, stress and anxiety in patients. The goal of this study is to explore as to whether participants who are suffering from cognitive (mental processing) impairment, and display symptoms of dementia responsive behaviors (RBD) like depression, stress and anxiety, show a response to TT. The study will also look at whether TT improves therapeutic relationships and allow the upkeep of a form of communication which may not be possible otherwise in patients with dementia and become an alternative treatment to medication.

Who can participate?
Older adults living in the SageCare Long Term Care Dementia Institution who have dementia and low mood

What does the study involve?
Participants are allocated to one of three groups. Those in the first group take part in TT on their neck and the shoulder. Those in the second group receive a mimic treatment that resembles TT (simple non-Therapeutic Touch). Those in the last group will be the control group and they take part in regular routine care. Participant's behaviour is monitored five days pre-treatment and five days post-treatment.

What are the possible benefits and risks of participating?
The possible benefits of TT are the improvement of behavioural symptoms of dementia such as agitation, wandering, restlessness, and vocalizations (making sounds that are not works), as well

as other symptoms that may contribute to RBD such as pain, sleep disturbances, depression, stress and anxiety will be investigated. There are no known risks to participating in the study.

Where is the study run from?
SageCare Long Term Care (Canada)

When is the study starting and how long is it expected to run for?
January 2017 to December 2021

Who is funding the study?
The College of Family Physicians Canada (Canada)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Therapeutic Touch in the management of Responsive Behavior in patients with Dementia

Acronym
TT in RBD

Study objectives
Therapeutic touch can be an effective non-pharmacological approach for the management of responsive behavior in patients with dementia with no negative sequelae.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Research Ethics Board Baycrest Health Sciences, 24/03/2017, ref: 16-56

Study design
Single centre double-blinded randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Quality of life

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Dementia

Interventions
Participants will be randomly divided into three groups. Each group will have around 25 participants.

Experimental Group: Will receive Therapeutic touch on the neck and the shoulder, twice a day. The participants receives therapeutic touch from a practitioner who will sense the imbalance in their energy field and use their hands to direct human energy to those areas for healing purposes. In regards to the administration of Therapeutic Touch, if the patient is awake, there would be a touch option available, defined as a very light touch over the feet, hands and shoulders. The Therapeutic Touch practitioner would place their hands over the body of the patient, starting from either the head or the shoulder, and making their way to the feet. The sessions are broken down into 4 phases. The assessment phase assesses the patient's energy field symmetry, since the purpose of Therapeutic Touch is to equalize the field. The clearing phase is about re-balancing the energy field. During the modulation phase, the Therapeutic Touch practitioner checks to see if there are any more imbalances and then focuses directly on those. Lastly, the reassessment phase is to see if the body feels different in any way than it did originally.

Non-Therapeutic Touch Group: Will receive a mimic treatment (simple non-Therapeutic Touch) that resembles Therapeutic touch, twice a day.

Placebo Group: Will receive regular routine care.

Each participant will require an approximately 30 minutes per session to administer and properly observe the effect of Therapeutic Touch. In addition, each participant's behavior will be observed every 20 minutes, for 10 hours a day during the five pre-intervention and five post-intervention days by trained and blinded observers.

Information collected during the Therapeutic Touch treatment session will include the session date, patient's goals for the treatment, patient response, and practitioner observations. All observers will be trained and masked during the study. Thus, they are not told the purpose of the study and the type and timing of the intervention. They will monitor and record each participant's behavior as per schedule during the five pre-intervention and five post-intervention days.

A follow up will take place 2 weeks after completion of the study. During the follow up, the observers will look to see if there is stability in symptoms control. They will look to see if an improvement in responsive behaviour(s) is maintained throughout the post-interventions. Moreover, observers will look to see if the participants have better symptoms control such as a decrease in agitation, restlessness, vocalizations, and wandering, as well as an improvement in pain control, sleep disturbances, and anxiety. Observers will also look to see if patients seem to be relaxed, and have established interpersonal relationships with the staff which will allow for better adherence with the care.

Intervention Type
Other

Primary outcome measure
Behaviour is assessed by the Modified Agitated Behaviour Rating Scale (ABRS) at baseline and five days post intervention.

Secondary outcome measures
Ability to form and establish interpersonal relationships is assessed by staff observations at baseline and five days post intervention.

Overall study start date
02/01/2017

Completion date
30/12/2021

Eligibility

Key inclusion criteria
1. Between the ages of 65 and 95, who have cognitive impairment and exhibit behavior symptoms of dementia
2. Reside in the SageCare Long Term Care Dementia Institution
3. Diagnosis of dementia according to the DSM IV criteria (confirmed by a physician)
4. Mini Mental state exam (MMSE) score < 20
5. Stabilized on medications for at least one month
6. Will remain on the unit for the duration of the study
7. Had resided on the unit for at least 2 months
8. Has multiple comorbidities

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
3 clusters, approximately 25 participants in each cluster, total 70-75 patients

Total final enrolment
92

Key exclusion criteria
1. Patients who have an acute psychiatric or physical illness
2. Patients who were diagnosed with dementia within a 3 month period

Date of first enrolment
01/02/2017

Date of final enrolment
01/01/2019

Locations

Countries of recruitment
Canada

Study participating centre
Sage Care
147 Elder St
North York
Canada
M2M 4G2

Sponsor information

Organisation
The College of Family Physicians Canada (CFPC)

Sponsor details
2630 Skymark Avenue
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Sponsor type
Government

ROR
https://ror.org/01dqayp38

Funder(s)

Funder type
Not defined

Funder Name
The College of Family Physicians Canada (CFPC)

Results and Publications

Publication and dissemination plan
All findings are published in a manuscript form or accepted for publication in a high-impact peer reviewed journal by this time. A poster will also be created by this date.

Intention to publish date
30/01/2022

Individual participant data (IPD) sharing plan
The extracted from electronic medical records and collected from the observations data will be de-identified and stored in the password protected electronic file on a secure computer server at the participating site.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		25/03/2022	13/07/2022	Yes	No