The Use of Randomized Controlled Trials in Advancing Cancer Nursing Research in Taiwan

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Taiwan Oncology Nursing Society (TONS)

Asian Oncology Nursing Society (AONS)
10 Leading Causes of Death in Taiwan, 2013

1. Malignant tumors (Cancer)
2. Heart diseases (excluding hypertensive diseases)
3. Cerebrovascular diseases
4. Diabetes
5. Pneumonia
6. Accidents
7. Chronic lower respiratory tract disease
8. Hypertensive disease
9. Chronic liver disease and cirrhosis
10. Kidney diseases (nephritis, nephritic syndrome and nephritis)

Mortality rate 661.3

(Per 100,000 population)

Source: Ministry of Health and Welfare
Date: 2014/09/04 update
Search: 2015/05/06
Top 10 Leading Cancer in Taiwan, 2013

1. Lung Cancer
2. Liver Cancer
3. Colorectal Cancer
4. Breast Cancer
5. Oral Cancer
6. Prostate Cancer
7. Stomach Cancer
8. Pancreatic Cancer
9. Esophageal Cancer
10. Cervical Cancer

Source: Ministry of Health and Welfare
Date: 2014/09/04 update
Search: 2015/05/06
Taiwan Cancer Center

- China Medical University Hospital
- Changhua Christian Hospitals
- Kaohsiung Veterans General Hospital
- Taipei Medical University Hospitals
- National Taiwan University Hospitals
- Hualien Tzu Chi Medical Center

A total of 24 Cancer Centers in Taiwan
Phases of Clinical Trials

**Preclinical (PHASES 1)**
- **Assess the Safety**
- **Days or Weeks**
- **Tens of participants**
- **Lab studies**
- **Several years**

**PHASES 1**
- **Test the Efficacy**
- **Weeks or Months**
- **Hundreds of participants**

**PHASES 2**
- **Involves Randomized and Blind testing**
- **Several years**
- **Thousands of participants**

**PHASES 3**
- **Post Marketing Surveillance Trails**
- **Ongoing**

**PHASES 4**
Why do RCTs?

- Level of Evidence
- Grade of Recommendation
- Advantages
- Disadvantages
Level of Evidence

Oxford Centre for Evidence-based Medicine
http://www.cebm.net

SIGN (Scottish Intercollegiate Guidelines Network)
http://www.sign.ac.uk

GRADE (Grading of Recommendations Assessment, Development and Evaluation)
http://www.gradeworkinggroup.org/
The Evidence Pyramid

Hierarchy of evidence: arranges study designs by their susceptibility to bias.
<table>
<thead>
<tr>
<th>Study design</th>
<th>Quality of evidence</th>
<th>Lower if</th>
<th>Higher if</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td>Risk of bias:</td>
<td>Larger effect</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Large</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td>+2 Very large</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Indirectness</td>
<td>Dose response</td>
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<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Evidence of a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td>gradient</td>
</tr>
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<td></td>
<td></td>
<td>imprecision</td>
<td>All plausible confounding</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-1 Serious</td>
<td>+1 Would reduce a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very serious</td>
<td>demonstrated effect or</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Publication bias</td>
<td>+1 Would suggest a</td>
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<tr>
<td></td>
<td></td>
<td>-1 Likely</td>
<td>spurious effect when</td>
</tr>
<tr>
<td></td>
<td></td>
<td>-2 Very likely</td>
<td>results show no effect</td>
</tr>
</tbody>
</table>

Advantages of RCT

- Internal Validity
- True measure of Efficacy
- Control of Exposure
- Causal Inferences

Bias: Selection bias, Performance bias, Attrition bias, Detection bias
## RCTs in Cancer vs Cancer Nursing

### Result Overview

<table>
<thead>
<tr>
<th>Step</th>
<th>Query</th>
<th>Count</th>
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<td>1 and 2</td>
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<td>4 and 5 and 6</td>
<td><strong>408</strong></td>
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</tbody>
</table>
Cancer Nursing Research in Taiwan - Intervention

- Exercise: 7
- Education: 6
- TPN: 3
- Music therapy: 2
- Psychotherapy: 2
- Acupressure: 2
- Other: 4

Other include:
- Biofeedback-relaxation
- Reflex therapy
- Massage
- Mouth care

N=26
Fundamentals of Randomized Controlled Trials

Protocol Development

Study Design

Randomization
- Randomization
- Sequence generation
- Allocation concealment

Blinding
- Single-blinded
- Double-blinded
- Triple-blinded

Control
- Control group type
- Source and control bias
- Adverse event (AE)

Endpoints
- Primary
- Secondary

Analysis
- ITT analysis
- PP analysis
- As-treated analysis
- Interim analysis
Study Design of RCTs

<table>
<thead>
<tr>
<th></th>
<th>Study Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Parallel Design</td>
</tr>
<tr>
<td>2</td>
<td>Cross-over Design</td>
</tr>
<tr>
<td>3</td>
<td>Factorial Design</td>
</tr>
<tr>
<td>4</td>
<td>Adaptive Design</td>
</tr>
<tr>
<td>5</td>
<td>Cluster Randomization Design</td>
</tr>
<tr>
<td>6</td>
<td>Multi-center Trial</td>
</tr>
<tr>
<td>7</td>
<td>Superiority, Equivalence and Non-inferiority Trials</td>
</tr>
</tbody>
</table>
1. Parallel Design

Two-arm design
- Randomization
- Intervention
- Control

Triple-arm design
- Randomization
- Intervention A
- Intervention B
- Control

- **Experimental group:** Yoga intervention
- **Control group:** Standard care
2. Cross-Over Design

• 2 × 2 Cross-Over Design
  2-sequence, 2-period, 2-treatment Cross-Over Design

Cross-over design: https://onlinecourses.science.psu.edu/stat509/book/export/html/123
Types of Cross-Over Design (1/2)

- Balaam’s design

2 × 2 Cross-Over Design

<table>
<thead>
<tr>
<th>Design 6</th>
<th>Period 1</th>
<th>Period 2</th>
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</thead>
<tbody>
<tr>
<td>Sequence AB</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Sequence BA</td>
<td>B</td>
<td>A</td>
</tr>
<tr>
<td>Sequence AA</td>
<td>A</td>
<td>A</td>
</tr>
<tr>
<td>Sequence BB</td>
<td>B</td>
<td>B</td>
</tr>
</tbody>
</table>

Table from: https://onlinecourses.science.psu.edu/stat509/node/
Types of Cross-Over Design (2/2)

- **Latin Squares**

<table>
<thead>
<tr>
<th>[Design 7]</th>
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<th>Period 2</th>
<th>Period 3</th>
<th>Period 4</th>
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<tr>
<td>Sequence ABCD</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Sequence BCDA</td>
<td>B</td>
<td>C</td>
<td>D</td>
<td>A</td>
</tr>
<tr>
<td>Sequence CDAB</td>
<td>C</td>
<td>D</td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Sequence DABC</td>
<td>D</td>
<td>A</td>
<td>B</td>
<td>C</td>
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</table>

<table>
<thead>
<tr>
<th>[Design 8]</th>
<th>Period 1</th>
<th>Period 2</th>
<th>Period 3</th>
<th>Period 4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence ABCD</td>
<td>A</td>
<td>B</td>
<td>C</td>
<td>D</td>
</tr>
<tr>
<td>Sequence BDAC</td>
<td>B</td>
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<td>A</td>
<td>C</td>
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<tr>
<td>Sequence CADB</td>
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<td>A</td>
<td>D</td>
<td>B</td>
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<tr>
<td>Sequence DCBA</td>
<td>D</td>
<td>C</td>
<td>B</td>
<td>A</td>
</tr>
</tbody>
</table>

Table from: https://onlinecourses.science.psu.edu/stat509/node/
3. Factorial Design

- 2 x 2 Factorial Design

<table>
<thead>
<tr>
<th>Treatment A</th>
<th>Treatment B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Both A &amp; B (Cell a)</td>
<td>B only (Cell b)</td>
</tr>
<tr>
<td>A only (Cell c)</td>
<td>Neither A nor B (Cell d)</td>
</tr>
</tbody>
</table>
Nurse-led telephone follow-up and an educational group programme after breast cancer treatment: results of a $2 \times 2$ randomised controlled trial. The European Journal of Cancer, 47(7), 1027-1036.

Example of Factorial Design

Follow up

- Arm 1 - Hospital follow-up
- Arm 2 - Telephone follow-up
- Arm 3 - Hospital follow-up + Educational
- Arm 4 - Telephone follow-up + Educational

EGP : Educational group programme
4. Adaptive Design

<table>
<thead>
<tr>
<th>Adaptive Randomization Design</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample Size Re-estimation Design</td>
</tr>
<tr>
<td>Group Sequential Design</td>
</tr>
<tr>
<td>Drop-the-loser Design</td>
</tr>
<tr>
<td>Adaptive Dose Finding Design</td>
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<tr>
<td>Biomarker-adaptive Design</td>
</tr>
<tr>
<td>Adaptive Treatment-switching Design</td>
</tr>
<tr>
<td>Hypothesis-adaptive Design</td>
</tr>
<tr>
<td>Adaptive Seamless Phase II/III Trial Design</td>
</tr>
<tr>
<td>Multiple Adaptive Design</td>
</tr>
</tbody>
</table>

5. Cluster Randomized Design

Methods

24 medical oncology clinics were cluster randomised in a 1:1 ratio, using a computer-generated sequence, stratified by clinic size and tumour site [four lung, eight gastrointestinal, four genitourinary, six breast, two gynaecological], to consultation and follow-up (at least monthly) by a palliative care team or to standard cancer care.
## 6. Multicenter Trial

**Structure of a typical multicenter**

<table>
<thead>
<tr>
<th>Level</th>
<th>Composition</th>
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</thead>
<tbody>
<tr>
<td>Oversight Level</td>
<td>Sponsoring organization</td>
</tr>
<tr>
<td></td>
<td>Steering committee</td>
</tr>
<tr>
<td></td>
<td>Planning subcommittee</td>
</tr>
<tr>
<td></td>
<td>Ethical subcommittee</td>
</tr>
<tr>
<td></td>
<td>Other subcommittee</td>
</tr>
<tr>
<td>Coordination Level</td>
<td>Clinical Coordinating Center</td>
</tr>
<tr>
<td></td>
<td>Other Center Agencies</td>
</tr>
<tr>
<td>Conduct Level</td>
<td>Site</td>
</tr>
</tbody>
</table>

Examples of Multicenter Trial

Fundamentals of Randomized Controlled Trials

Study Design

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Control
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- Adverse event (AE)

Endpoints
- Primary
- Secondary

Analysis
- ITT analysis
- PP analysis
- As-treated analysis
- Interim analysis
1. Randomization

- Common type of randomization methods are:

  - Simple Randomization
  - Block Randomization
  - Stratified Randomization
  - Adaptive Randomization

Reference:
Block Randomization

- Block size: 4

- Possible balanced combinations

- Random selection of block assignment of all participants

= Control  = Treatment
Example for Randomization


Participants were randomized in blocks of four to ensure even distribution of age, gender, and the number of participants in control and experimental groups.
2. Sequence Generation

Adequate

- Computer random number generator
- Random number table
- Stratified / Block randomization
- Minimization
- Low tech: coin toss, shuffling cards or envelopes, drawing lots...

Inadequate

- Quasi-random: date of birth, day of visit, ID or record number, alternate allocation...
- Non-random: choice of clinician or participant, test results, availability

Reference: The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials
3. Allocation Concealment

**Adequate**
- Central allocation
- Sequentially-numbered, Opaque, Sealed, Envelopes (SNOSE)
- Sequentially numbered, identical drug containers

**Inadequate**
- Random sequence known to staff in advance
- Envelopes or packaging *without* all safeguards
- Non-random, predictable sequence

Reference: The Cochrane Collaboration’s tool for assessing risk of bias in randomised trials

The researchers used a computer to generate a randomisation list featuring four-person blocks before performing the experiments; the lists of the various groups were then sealed inside opaque envelopes. During pretest data collection, one of the researchers opened the envelopes and randomly assigned participants to the walking-exercise or the usual-care group.
Fundamentals of Randomized Controlled Trials

Study Design

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Blinding

- **Participants**
- **Investigator** (Treatment team/evaluator)
- **Monitoring Committee** (Sponsor/Data reviewer...various meanings)

**Blinding Types:**
- Single blind
- Double blind
- Triple blind
Lo, et al. (2012). Therapeutic efficacy of traditional Chinese medicine, Shen-Mai San, in cancer patients undergoing chemotherapy or radiotherapy: study protocol for a randomized, double-blind, placebo-controlled trial, Trials, 13(232), 1-6.

**Blinding**

The patients will receive capsules either with SMS or placebo. These capsules are the same in appearance, color and shape. **The researchers and patients** will not know which group the patients are allocated to from the appearance of the medication given.
Fundamentals of Randomized Controlled Trials

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- Adverse event (AE)

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Analysis
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- PP analysis
- As-treated analysis
- Interim analysis
Control Group Type

- Placebo concurrent controls
- Dose comparison concurrent controls
- No treatment concurrent controls
- Active (Positive) treatment comparator control
  - Superiority
  - Equivalence
  - Non-Inferiority
Source and Control Bias

Type of Bias:
- Selection
- Performance
- Attrition
- Detection

Patient Sample:
- Target Population
- EG (Experimental Group)
- CG (Control Group)
- Intervention (Experimental)
- Follow-up
- Data Analysis
- Intervention (Control)
- Follow-up
- Data Analysis

Precautions:
- Randomization
- Double Blind
- ITT analysis
- Outcome assessor blind

EG: Experimental group; CG: Control group
Fundamentals of Randomized Controlled Trials

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- Interim analysis
Endpoints

Primary Endpoints

- Primary endpoint = Efficacy variable
- Most important outcome, Target variable

Secondary Endpoints

- Related to the primary objective.
- Related to the secondary objectives.
- The number of secondary variables should be limited.
Intervention Outcomes in Cancer Nursing Research

Treatment and disease related symptoms
- Nausea
- Vomiting
- Pain
- Coughing
- Nutritional measures (Body weight)

Functional adjustment
- Behavioral
- Physical functions
- Socializing
- Going back to work

Medical
- Leukocyte activity
- Tumor response to C/T
- Physician rating of disease progression
Intervention Outcomes in Cancer Nursing Research

Emotional adjustment
- Anxiety
- Depression
- Fatigue
- Fear
- Self-esteem
- Locus of control
- Satisfaction with medical care
- Other attitudes

Other
- Quality of life (QoL)
- Survival time
- Recurrence
- Well-being
- Sleep disturbances
Fundamentals of Randomized Controlled Trials

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- Interim analysis
Per Protocol (PP Analysis)

• PP Analysis: only those who actually complete the treatment.
As Treated Analysis

- As Treated Analysis: the subject according to whether they received the treatment or not.
The ITT Analysis all persons randomized even if some drop out before complete of treatment.
Example for ITT Analysis

Effects of massage on pain, mood status, relaxation, and sleep in Taiwanese patients with metastatic bone pain: A randomized clinical trial.

Critical Appraisal
• Consolidated standards of reporting trials statement, CONSORT statement

• 2010 CONSORT Statement include two parts:

1. Checklist
   • Title and abstract
   • Introduction
   • Methods
   • Results
   • Discussion
   • Other information

2. Flow diagram

**Cancer Nursing of RCTs Flow Diagram in USA**

Articles identified through database searching (*n* = 639)

The first stage of screen
- Articles excluded (*n* = 355):
  - Having full-text but not eligible (*n* = 98)
  - Not having full-text and not eligible (*n* = 196)
  - Not having full-text but potentially eligible (*n* = 61)

Articles screened (*n* = 284)

The second stage of screen
- Articles excluded (*n* = 63):
  - Secondary analysis (*n* = 30)
  - Non-RCT study (*n* = 32)
  - Non-nursing study (*n* = 1)

Primary sources of the secondary analysis articles (*n* = 6)

**Eligible articles (*n* = 227)**
Cancer Nursing Research in Taiwan - Intervention

N=26

Other include:
- Biofeedback-relaxation
- Reflex therapy
- Massage
- Mouth care

Number of Classification:
- Exercise
- Education
- TPN
- Music therapy
- Psychotherapy
- Acupressure
- Other
1. Title and Abstract

- 1a Identification as a **randomized trial** in the title
- 1b **Structured summary** of trial design, methods, results, and conclusions

![Diagram showing ONR and Taiwan percentages for 1a and 1b criteria.](image-url)
2. Introduction

• Background and objectives
  2a Scientific **background** and explanation of rationale.
  2b Specific **objectives** or hypotheses

<table>
<thead>
<tr>
<th>Item</th>
<th>ONR (n=227)</th>
<th>Taiwan (n=26)</th>
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<tr>
<td></td>
<td>$n$</td>
<td>%</td>
</tr>
<tr>
<td>2a</td>
<td>225</td>
<td>99</td>
</tr>
<tr>
<td>2b</td>
<td>223</td>
<td>98</td>
</tr>
</tbody>
</table>
# 3. Method

- Trial design
- Participants
- Interventions
- Outcomes
- Sample size
- Randomization
- Blinding
- Statistical methods
3a Description of trial design (such as parallel, factorial) including allocation ratio.

<table>
<thead>
<tr>
<th>Item</th>
<th>ONR (n=227)</th>
<th>Taiwan (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>3a</td>
<td>38</td>
<td>17</td>
</tr>
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</table>
Cancer Nursing Research in Taiwan - **Outcome** \(N = 26\)

### Treatment and disease related symptoms
- Pain
- Nausea
- Vomiting
- Fatigue

### Emotional adjustment
- Anxiety
- Depression
- Coping

### Others
- Well-being
- Cortisol
- Sleep quality
Method-Randomization

Sequence Generation

- 8a Method used to generate the random allocation sequence
- 8b Type of randomization; details of any restriction (such as blocking and block size)

<table>
<thead>
<tr>
<th>Item</th>
<th>ONR (n=227)</th>
<th>Taiwan (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>8a</td>
<td>83</td>
<td>37</td>
</tr>
<tr>
<td>8b</td>
<td>90</td>
<td>40</td>
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9 Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned.
11a If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how

<table>
<thead>
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<th>Taiwan (n=26)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>11a</td>
<td>43</td>
<td>19</td>
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</table>
## 4. Results

- Participant flow
- Recruitment
- Baseline data
- Number analyzed
- Outcomes and estimation
- Ancillary analysis
- Harms
Results—Participant Flow

13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome.

13b For each group, losses and exclusions after randomization, together with reasons.
<table>
<thead>
<tr>
<th>CONSORT statement</th>
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<th>ONR (n=227)</th>
<th>Taiwan (n=26)</th>
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<tbody>
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<td></td>
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<td>%</td>
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<tr>
<td>Title and Abstract</td>
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Conclusion

1. There is a need to compile more well-designed RCTs in cancer nursing research.
2. More attention needs to be given to the appropriate use of methods in developing RCTs.
3. There is a great need for innovative designs such as cluster randomized design and multicenter research designs.
4. Guidelines regarding these aspects of RCTs must be developed accordingly.
Evidence-Based Health Care Platform (EBHC) in Taiwan

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Closing the gap: from evidence to practice

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- TJBCC

Nursing Organizations
- TACCA, TONS, TAHPN, TANA, TWOCNA
- TCMNA, TNNA, TANA, ACSHA, TOHNA, TANP, TNMA, TAOHN, TNIA, PMHNA, STTI, TCTNA, TMBN, TANE

Customers: People
WE KNOW WE CAN DO IT, AND WE CAN DO IT BETTER,.

Debbie Moore
Thanks for your attention!!