A mixed-methods research process to develop a complex intervention

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A mixed-methods qualitative research study to develop a complex intervention for weight loss and anorexia in advanced cancer: The Family Approach to Weight and Eating

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Abstract

Background: Worldwide, most people with incurable cancer experience weight loss and anorexia. These symptoms can occur in patients and their family caregivers. Interventions that take account of the relationship between patient and family caregiver could improve outcomes for both members of this dyad.
The problem
The problem

Patient impact

- Anxiety\textsuperscript{1}
- Distress\textsuperscript{2-4}
- Challenge to identity\textsuperscript{5}
- Negative body image\textsuperscript{6}
- Sense of helplessness\textsuperscript{7}
- Loss of control\textsuperscript{7}
- Thoughts of death\textsuperscript{7}

I don’t want the things you dish up.
It’s only porridge like you had in the hospice!

Cancer cachexia syndrome

Primary
Metabolic change
↓ Treat

Secondary
Malnutrition
↓ Feed

Tertiary
Distress
↓ Support

What did we know in 2008?

- Weight loss and anorexia are problems for both patients with cancer and their family members\textsuperscript{1,2}
- There is a relationship between patient and carer experience of distress in cancer\textsuperscript{3}
- Family interventions have been found effective in improving symptom management in conditions other than cancer\textsuperscript{4}

Question

Can an intervention to support the family-management of cachexia-related problems mitigate distress and improve quality of life for patients and their family members?
Developing a complex intervention

Continuum of increasing evidence

Phase 0
Theory

Phase I
Modelling

Phase II
Exploratory trial

Phase III
RCT

Phase IV
Implement
PHASE I

Sub-project 1
Macmillan Weight and Eating Studies: findings

Sub-project 2
Systematic Review: Family interventions in cancer

Sub-project 3
Systematic Review: What to eat when living with cancer

Sub-project 4
Understanding theory and practice of family therapies

PHASE II

FAWE prototype

Refinement in practice

PHASE III

Critical review

FAWE
Phase I: methods

Sub-project 1
Macmillan Weight and Eating Studies: findings and secondary analysis

Sub-project 2
Systematic Review: Family interventions tested in cancer

Sub-project 3
Systematic Review: What to eat when living with cancer

Sub-project 4
Understanding theory and practice of family therapies

Sub-project 5
Identification and synthesis of activities and techniques theoretically able to mitigate distress in patients with advanced cancer and family carers affected by weight loss and/or poor appetite

FAWE prototype
MAWE: Secondary analysis

MAWE STUDY: 65/91 (71%) of newly referred patients agreed to participate

<table>
<thead>
<tr>
<th>Patient sample characteristics (n=36)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td>44-84 years</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
</tr>
<tr>
<td>Eating-related distress (mean (range))</td>
<td>3.2 (0-10)</td>
</tr>
<tr>
<td>Weight-related distress (mean (range))</td>
<td>2.2 (0-10)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Carer sample characteristics (n=36)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td>32-85 years</td>
</tr>
<tr>
<td>Female</td>
<td>29</td>
</tr>
<tr>
<td>Eating-related distress (mean (range))</td>
<td>4.7 (0-10)</td>
</tr>
<tr>
<td>Weight-related distress (mean (range))</td>
<td>4.6 (0-10)</td>
</tr>
</tbody>
</table>
The wife has spent the last few months cooking three meals a day for me. She goes out of her way. She produces a wonderful meal and it ends up in the bin because I just can’t eat it…She is suffering more than I am from this. (Fred)
### Categories of interdependency in distress

<table>
<thead>
<tr>
<th>Patient concern/distress</th>
<th>Carer concern/distress</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pressure to eat from carer</td>
<td>Trying and failing to feed</td>
</tr>
<tr>
<td>Got to survive</td>
<td>Got to eat for health/survival</td>
</tr>
<tr>
<td>Embarrassment</td>
<td>Constant feeding watch</td>
</tr>
<tr>
<td>Guilt</td>
<td>Anticipating loss</td>
</tr>
<tr>
<td>Carer food intake</td>
<td>Decline in own food intake</td>
</tr>
<tr>
<td>Carer suffering</td>
<td>Helplessness</td>
</tr>
<tr>
<td>Relationship with carer</td>
<td>Relationship with patient</td>
</tr>
</tbody>
</table>
WEIGHT LOSS AND/OR CHANGING EATING HABITS

MEANINGS

DISTURBED INTERACTIONS

ACCEPTANCE

RESISTANCE

AIDED INTERACTIONS

DISTRESS

Systematic review: family interventions in cancer

What family focused psychosocial interventions have been tested in the context of cancer care for symptoms and other health problems experienced by patients and/or their family members?

Findings:

- Emotional health and well-being were improved in 13/22 studies
- In all studies with measured effect on anxiety, depression or distress the intervention included the enhancement of couple communication
- 2/5 studies comparing individual versus couple intervention found the couple-focused approach superior

Systematic review: what to eat?

What are the outcomes of planned additions to or omissions from the diet of people off treatment living with cancer and involuntary weight loss?

Physical outcome focused advice

Psychosocial outcome focused advice

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diagnosis

\[\text{curable} \quad \text{incurable}\]

death

nutrition dense diet, achieved by nutritional counselling to
i/ educate on the fortification of foods
and ii/ advise frequent eating.

‘eat what you want’.

Understanding the theory and practice of family therapy

- Family interaction course: Tavistock Institute, London

- Observation of community specialist palliative care nurses working with dyads

- Observation of a family therapist and team working with adolescent-parent dyads using a systemic approach
Fitting the pieces together
BRINGING IT ALL TOGETHER: The prototype

Education and Aided Talk (EAT) helps with adjustment by working with resistance to disrupted interactions. Its components are: information and advice on appropriate diet, normalising change using storied examples, facilitating conflict resolution using perspective taking, and supporting relationships by aiding the recognition and planning of ways of helping others to live with feelings about food.
Phase II: practice and modification of the prototype

Refinement of FAWE in practice
Clinical nurse specialists identified 20 patient-carer pairs
1/20 was found during the FAWE consultation to be non-cancer
2/20 died and 1/20 withdrew before their FAWE consultation

<table>
<thead>
<tr>
<th>Patient sample characteristics (n=16)</th>
<th></th>
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<tbody>
<tr>
<td>Age range</td>
<td>41-84 years (median 71)</td>
</tr>
<tr>
<td>Female</td>
<td>7</td>
</tr>
<tr>
<td>Weight loss &gt;5% over 6 months</td>
<td>10/12 (range 5% to 21% median 9%)</td>
</tr>
<tr>
<td>Eating-related distress</td>
<td>2.5 (range 0 to 8.5)</td>
</tr>
<tr>
<td>Weight-related distress</td>
<td>2 (range 0 to 7.5)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Carer sample characteristics (n=16)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Age range</td>
<td>43-85 years (median 73)</td>
</tr>
<tr>
<td>Spouse</td>
<td>13</td>
</tr>
<tr>
<td>Daughter</td>
<td>3</td>
</tr>
<tr>
<td>Eating-related distress</td>
<td>6.7 (range 0.5 to 10)</td>
</tr>
<tr>
<td>Weight-related distress</td>
<td>5.1 (range 0.5 to 10)</td>
</tr>
</tbody>
</table>
Modification: example 1

In the past 3 days

How much concern has eating caused you?

How much distress has eating caused you?

No concern | Extreme concern

No distress | Extreme distress
Eating map

YESTERDAY

What’s the same?

What’s changed?

BEFORE CANCER

Patient:

Patient:

Carer:

Carer:
Modification: example 2 - building in evaluation

Interview Schedule: Section C

1. Benefits of the activity

   Has the story, and our conversation, shed any light on your own experiences?

2. Problems completing the activity

   What was surprising about the story? And our discussion?

3. Change that may result from engaging in the activity

   Do you think you may do anything different following our meeting today?

4. What the process and outcomes might be for other families

   What about others? Do you think there could be any down side for other couples? Do you think there could be any benefit for other couples?
### Findings: potential benefit or harm?

<table>
<thead>
<tr>
<th>Deliverability:</th>
<th>15/16 patient-carer pairs</th>
</tr>
</thead>
</table>
| Acceptability:  | 1/16 patients considered talking about emotions pointless  
|                 | 1/16 carers could not see how talking could be helpful |
| Perceived benefits: | 12/16 patients described one or more benefits  
|                 | 14/16 carers described one or more benefits |
| Perceived harms: | 1/16 carers suggested FAWE might provoke conflict over food  
|                 | 3/16 carers suggested the story might make carer feel guilty  
|                 | 3/16 patients suggested FAWE provoked sadness/discomfort |

**Story can only help because it can give ideas of how to combat problems; ideas to try.**

**Story might make carers feel upset, but anything you read about the illness can do this.**
Phase II: the end point

i/ deliverable by a clinician-researcher

ii/ acceptable to patients and carers

iii/ may mitigate weight- and eating-related distress
Phase III

Critical review

FAWE
EAT?: Prototype 3.

Mapping of eating change

Questions to facilitate perspective taking

Story

Questions to facilitate talk about i) feelings and food
   ii) reciprocity

Review

Questions to facilitate reflection on talk about story
and identification of ways patient and carer help each
other with weight and eating problems

Information - verbal and written, if appropriate
### Phase III: managing the uncertainties

<table>
<thead>
<tr>
<th>General questions</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EAT or EAT?</strong>&lt;br&gt;The intervention is not about feeding. Does the acronym need the question mark, or is the question mark confusing?</td>
<td></td>
</tr>
<tr>
<td>With one exception (a patient), the 16 patients and carers who have tried out the activities have loved the stories and the DVD. In your opinion, is it better to work with a DVD clip or a story? Why?</td>
<td></td>
</tr>
<tr>
<td>Could EAT be offered to individual patients or carers (it’s not always possible to talk to patient-carer pairs)?</td>
<td></td>
</tr>
</tbody>
</table>
Step one
Aiding patient and family carer to talk about ‘my perspective’

Sharing perspective tool

Or

Mapping changing eating habits tool

**SHARING PERSPECTIVES**
I am interested in your eating habits. Some people have concerns about eating. I would like to find out if either of you have concerns about (patient’s name) eating using this scale.

1. **Patient question:** How much concern have you had about eating?

**Mapping changing eating habits**
I am interested in your eating habits. I would like to know more about what you are both eating at the moment and how this compares with what you ate before (patient) became unwell.

I have a chart for us to complete together. Here it is:

<table>
<thead>
<tr>
<th>No Concern</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eating map</td>
</tr>
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**YESTERDAY**          **BEFORE CANCER**
Step two

Aiding patient and family carer to think about ‘other perspectives’

Story

Or

DVD

The story/DVD presents common weight- and eating-related problems for families affected by advanced cancer
Step three

Aiding patient and family carer to talk about ‘feelings, food and reciprocity’

Questions about the story/DVD

Biographical questions

Evaluation questions

If appropriate give advice about involuntary weight loss and eating well with advanced cancer
What next?

- **Phase II trial?**

- **Further development, as a component of multimodal intervention for cancer cachexia?**

- **Foundation for a patient-carer decision aid?**

- **A model for clinical consultations** with patient-carer dyads with competing views on difficult to manage problems?
Thank you

For more information:


http://www.cancercachexia.com/

Contact  HopkinsonJB@cardiff.ac.uk

Conflict of Interest: Jane Hopkinson is a member of the Scientific Board, Cachexia Hub, Helsinn Healthcare.