Symposium

Developing bespoke self-management interventions in people with long-term conditions: Using mixed methods to apply and elaborate on different components of the MRC framework
Developing bespoke self-management interventions in people with long-term conditions: using mixed methods to apply and elaborate on different components of the MRC framework
Overview of the health psychology section at KCL

• Who are we?
  – Health psychologists
  – Clinical psychologists
  – Statisticians

• Who do we work with?
  – People with physical long-term conditions (LTCs)
  – Front line NHS staff in primary and secondary care
  – Patient and public involvement groups
  – National NHS initiatives e.g. IAPT
  – Multi-disciplinary researchers
  – King’s Health Partners
Overview of the health psychology section at KCL

• What do we do?
  – Develop **tailored** psychological interventions to help people manage their LTC over time (distress, symptoms, quality of life, adherence)
  – **Integrate** the management of physical and mental health
  – **Train** front line NHS staff to become skilled in the delivery of psychological interventions and Stage I MSc Health Psychology Students

• How do we do it?
  – Develop **LTC specific theoretical models** to identify **unique** treatment targets for our outcome of interest
  – **Adapt** psychological treatment techniques to the illness population, whilst adhering to our **illness and treatment models**
  – Study in depth, **mechanisms of action, process outcomes and intervention fidelity**
  – Continuously **refine** our theory and treatment interventions after trial evaluation
Objectives of our symposium

To provide examples of the application of the Medical Research Council framework for the design of complex interventions in people with physical LTCs

**Development**
To elaborate on methodological procedures used to identify and develop theory. “Bottom up” and “Top down” examples are provided.

**Feasibility and piloting**
To provide an example of a feasibility study in chronic pain and reflect on the challenges identified from the patient and NHS staff perspective.

**Evaluation**
To explore how effectiveness and change processes are evaluated in the context of a cognitive behaviour therapy intervention for hot flushes.

**Implementation**
To discuss how findings are translated into real world settings outside of the study context.

Medical Research Council (2006)
Psychosocial impact of food and nutrition in people with inflammatory bowel disease (IBD): a “bottom-up” approach to intervention development

Dr Lyndsay Hughes
Lyndsay.Hughes@kcl.ac.uk
Overview of talk

• To give an example of a “bottom up” theoretical model development

• To explain the concept of food related quality of life in IBD

• To discuss some potential areas for intervention development to address poor food related quality of life
What is IBD?

- Inflammatory Bowel Disease (IBD) is an autoimmune condition affecting ~1% of the population
- Symptoms: abdominal pain, diarrhoea/urgency, anorexia, weight loss, abscesses/fistulas among others
- Often confused with IBS but aetiology and prognosis differ significantly
Food related quality of life (FRQoL) in IBD

- Limited evidence around any causal relationship between eating and drinking and symptoms

- UK IBD standards recommend all IBD patients should have access to nutritional support and advice from a specialist dietitian

- Focus groups (Prince et al., 2011) suggest that all aspects of eating and drinking are of concern to IBD patients and they would welcome more research and support in the area
AIMS

Use a bottom-up approach to investigate a problem identified by patients:

1) Establish what FRQoL means to IBD patients
2) Develop a new questionnaire to measure FRQoL in IBD
3) Identify whether there is a need to address poor FRQoL in IBD
4) Pinpoint areas for possible intervention
Qualitative study

• **Eating and drinking with IBD**

  • “*There are certain things that I simply will not touch. As I say, you know, curry and chili and what have you = even when I’m feeling well, they will have a very bad effect on me*” (female, CD)

  • “*I am kind of boring, but then I have to be kind of boring – very plain food and always the same sort of food...*” (male, UC)

  • “*If I’m going out in a sociable way – I don’t know to a bar or to a wedding or wherever – then I’ll tend not to eat before just so that there’s nothing in my stomach*” (female, CD)
Qualitative study

- **Social effects of eating and drinking**

  - “I mean colleagues sometimes go out and they invite me and I do find excuses. I’d like to go but then it’s just too messy” (female, CD)

  - “Eating out is much, much harder. And I’m only just starting to get to grips with that” (male, CD)

  - “If you’re a woman, you know, and you’re not drinking, people start making assumptions about ‘Oh, is she pregnant and is it going to impact on her career?’” (female, UC)
Qualitative study

Psychological aspects of eating and drinking

• “Frustration massively. It’s aggravating because you can’t plan your life or do anything you want to do because you’ve got to plan everything around what you’re body is going to do” (male, CD)

• “I just have to think – is the short term really going to be worth what happens afterwards?” (female, CD)

• “It does vary on a day to day basis and that’s probably the hardest part because there are times you know there are certain things that are going to cause a reaction... it’s all a learning process” (male, UC)
Results of qualitative study

Main findings:

1. Disordered eating persists even in remission, particularly for CD
2. Social interaction is difficult – socialising often revolves around eating/drinking, non-disclosure, others’ assumptions
3. Unpredictability, lack of knowledge/advice, planning and frustration reduce enjoyment of eating and drinking

Poor FRQoL appears to be a persistent problem in IBD
Developing a new FRQoL questionnaire

- Items developed from literature review, interviews, expert input and 100 IBD patients

- 314 IBD patients, 100 asthma patients, 117 healthy volunteers completed 41 item questionnaire and others including brief IPQ, HADS and SF36

- Questionnaire reduced to 29 items through EFA, good reliability and validity
## Quantitative study

<table>
<thead>
<tr>
<th>Variable</th>
<th>B</th>
<th>SE B</th>
<th>β</th>
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</thead>
<tbody>
<tr>
<td><strong>Step 1</strong></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Gender</td>
<td>13.79</td>
<td>3.53</td>
<td>.25*</td>
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<tr>
<td><strong>Step 2</strong></td>
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<td></td>
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<tr>
<td>Gender</td>
<td>10.26</td>
<td>2.92</td>
<td>.18*</td>
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<td>Anxiety</td>
<td>1.92</td>
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<td>.32*</td>
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<td>Depression</td>
<td>2.23</td>
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<td><strong>Step 3</strong></td>
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<tr>
<td>Gender</td>
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<td>Anxiety</td>
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<td>-.99</td>
<td>.15</td>
<td>-.36*</td>
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<td>IPQ consequences</td>
<td>4.11</td>
<td>.63</td>
<td>.35*</td>
</tr>
<tr>
<td>Disease activity</td>
<td>3.52</td>
<td>3.54</td>
<td>.04</td>
</tr>
<tr>
<td>Nutritional score</td>
<td>6.50</td>
<td>4.04</td>
<td>.07</td>
</tr>
</tbody>
</table>

Note. $R^2=0.061$ for Step 1; $\Delta R^2=0.316$ for Step 2; $\Delta R^2=0.259$ for Step 3 ($p<0.001$)

*p<0.05
Potential factors related to FRQoL
## What do we know so far?

<table>
<thead>
<tr>
<th>Potential risk factors of poor FRQoL</th>
<th>Potential outcomes of poor FRQoL</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Being female</td>
<td>• Social isolation</td>
</tr>
<tr>
<td>• Having Crohn’s Disease</td>
<td>• Conflict</td>
</tr>
<tr>
<td>• Anxiety</td>
<td>• Behavioural restrictions</td>
</tr>
<tr>
<td>• Higher consequences perceptions</td>
<td>• Malnutrition</td>
</tr>
<tr>
<td>• Previous adverse experiences</td>
<td>• Psychological distress</td>
</tr>
<tr>
<td>related to eating and drinking</td>
<td></td>
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</tbody>
</table>
Potential areas for intervention

Could include:

- Communication training/disclosure
- Developing balanced rather than all-or-nothing behaviour
- Managing anxiety around eating and drinking in public
- Incorporating aspects of CBT
- Healthy eating

- Important that any intervention would be multidisciplinary and tailored to the individual
Benefits of using a bottom-up approach

• An under-represented phenomenon has been identified and started to be developed
• Qualitative work gives us an in-depth understanding of what is important to patients
• A new questionnaire allows us to measure the phenomenon for future work
• FRQoL doesn’t appear to be explained by existing models or theories
• Work presented gives preliminary indication of areas to target for intervention
Using the common sense model and patient and public involvement to develop an online cognitive-behavioural therapy (CBT) intervention for managing distress in dialysis

Dr Joanna Hudson
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Focus of talk

Development
To elaborate on methodological procedures used to identify and develop theory. “Bottom up” and “Top down” examples are provided.

Feasibility and piloting
To provide an example of a feasibility study in chronic pain and reflect on the challenges identified from the patient and NHS staff perspective.

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Medical Research Council (2006)

- The team: Joseph Chilcot, Rona Moss-Morris, Amy Carroll, David Game, Matthew Hotopf, Judy Joseph, Lucy Yardley
What is end-stage renal failure and dialysis?

- End-stage renal failure (ESRF) = chronic condition

- Affects kidneys ability to filter the body’s waste products and excess fluid

- Without treatment physical health rapidly deteriorates

- Dialysis = treatment for ESRF + lifestyle change

- Dialysis works like an artificial kidney to remove toxic waste products and excess fluid

- Haemodialysis: 3-5 hours, 3 times per week
Distress in dialysis and its treatment

High prevalence of distress in dialysis population: ~40%

Cognitive-behavioural therapy is a treatment option for managing distress in dialysis

How can we tailor CBT to the needs of the ESRF population?
Literature review

• To identify ESRF specific correlates of distress in dialysis (haemodialysis and peritoneal dialysis)

• Based on constructs outlined in the common-sense model

• Health threats

• Illness specific cognitions

• Coping behaviours
ESRF specific health threats

• Critical illness events
  – Dialysis initiation

• Ongoing ESRF stressors
  – Lifestyle changes
  – Dialysis attendance
  – Change in body image
  – Burden to others
  – Waiting for transplant
  – Experience of physical symptoms
ESRF specific cognitions

- Seven cross sectional studies: the distressed cognitive profile:

  - Low levels of treatment efficacy (n=2)
  - Perceived lack of understanding of ESRF (n=2)
  - Low perceptions of personal control over ESRF (n=3)
  - Believing ESRF to be unpredictable (Timeline cyclical; n=3)
  - Greater perceived physical and social consequences (N=7)
  - More symptoms attributed to ESRF (Identity: n=3)
ESRF coping behaviours

• Managing ESRF
  – Lower levels of distress were observed with:
    – Greater use of active coping (n=4; cross-sectional)
    – Greater use of planning (n=2; cross-sectional)

• Managing distress
  – Lower levels of distress were observed with:
    – Positive reinterpretation and growth/reappraisal (n=3; cross-sectional)

• Role of emotion-focused coping=unclear
### Improving Distress in Dialysis Treatment model (iDiD)

<table>
<thead>
<tr>
<th>Short-term: critical illness events</th>
<th>Long-term: illness related challenges</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Initiation of dialysis</td>
<td>- Attending for dialysis</td>
</tr>
<tr>
<td>- Changes in body image (generation of fistula)</td>
<td>- Managing food restrictions &amp; thirst</td>
</tr>
<tr>
<td></td>
<td>- Waiting for a transplant</td>
</tr>
<tr>
<td></td>
<td>- Changes in body image (weight loss/gain)</td>
</tr>
<tr>
<td></td>
<td>- Experience of physical symptoms</td>
</tr>
<tr>
<td></td>
<td>- Burdening others</td>
</tr>
</tbody>
</table>

- Poor sleep
- Impaired cognitive functioning

#### Illness management
- Low use of:
  1. behaviours targeting source of distress
  2. Planning
  3. Positive reinterpretation and growth

#### Social interactions
- Low quality of:
  1. Social interactions
  2. Social support

- Cycle of distress initiated or sustained
- Attributing a high number of symptoms to ESKD
- Thinking ESKF is unpredictable
- Perceiving there to be a high number of consequence of ESKD for physical and social functioning
- Thinking they have little control over ESKD
- Believing treatments to be ineffective
- A perceived poor understanding of ESKD

#### Physical symptoms

#### Experience of psychological distress

#### Illness management coping behaviours & social interactions

#### Typical cognitive profile
Translated into seven online sessions

1. Session 1: What is end-stage renal failure?
2. Session 2: Why do I feel distressed?
3. Session 3: Dealing with my negative feelings?
4. Session 4: Tackling unhelpful thoughts about end-stage renal failure?
5. Session 5: Goal setting and problem solving
6. Session 6: Managing difficult social relationships
7. Session 7: Progress recap & preparing for the future
Patient and public involvement

Jane's problem & how she followed the seven steps

Step 6: Put in place your plan of action and write down your thoughts and feelings about how it went.

I spoke to the renal nurse on Wednesday. I felt relieved as she reassured me that other people find it hard. I met with the dietician the next week and she taught me about compensatory behaviours. She talked me through the diagram below. I learnt that I can drink less the day before a special meal so that I can use the fluid that I saved the following day.

- Most days: Try to stick to your recommended fluid allowance.
- Day before special meal: Halve your daily fluid (liquid) allowance in advance of your family meal on Friday.
- Day of special meal: Add the fluid (liquid) allowance you saved from Thursday onto your daily allowance for Friday.
### Application of the health psychology section approaches

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
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<tbody>
<tr>
<td>What was our over-arching theoretical model of illness/outcome?</td>
<td>Common sense model (CSM)</td>
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<tr>
<td>How was the theoretical model refined for our LTC population?</td>
<td>Dialysis specific health threats, CSM thought content, and coping behaviours</td>
</tr>
<tr>
<td>What will be our theoretical treatment model?</td>
<td>CBT</td>
</tr>
</tbody>
</table>
| How can intervention techniques for our treatment models be modified in light of our model development? | - Concrete examples of dialysis specific critical events given  
- Thought content relevant to ESRF addressed  
- ESRF specific coping behaviours and patterns addressed |
| What mechanisms of action, process outcomes, intervention fidelity checks will be done? | - Illness cognitions  
- Adherence to the intervention (patient)  
- Adherence to the intervention (practitioner)  
- Qualitative interviews with patients |
A brief physiotherapist delivered treatment informed by acceptance and commitment therapy for patients with chronic low back pain: the PACT study

Dr Emma Godfrey
Emma.Godfrey@kcl.ac.uk
Overview of talk

• To provide an example of a feasibility study in chronic low back pain

• To discuss how acceptance and commitment therapy was adapted to be delivered by physiotherapists

• To provide examples of physiotherapist and patient reflections about the feasibility and acceptability of the intervention
Chronic Low Back Pain in the UK

- Annually, 1.26 million patients seek physiotherapy for CLBP at a cost of £150 million (Maniadakis and Gray, 2000)

- Standard physiotherapy is moderately effective in improving physical functioning (Artus et al., 2010)

- Need to build on existing services and help patients to self-manage
Psychological Approaches to CLBP Treatment

- Cognitive Behavioural Therapy (CBT) good evidence for treating chronic pain (Eccleston et al, 2009)

- CBT delivered by physiotherapists produces only modest improvements in CLBP (BeST Trial, Lamb et al 2010)

- Acceptance and Commitment Therapy (ACT) promising theory led approach with good evidence base (Veehof et al, 2011)

- Can ACT be adapted for physiotherapists treating CLBP?
To improve **function** and **psychological well-being** by:

- Encouraging acceptance to lessen focus on and struggle with pain
- Promoting the pursuit of valued goals to facilitate resumption of normal activities
- Supporting the self-management of CLBP
Theoretical content of PACT

• Central to ACT – changing behaviour through enhancing psychological flexibility in both patient and practitioner

• Adapted ACT for non-mental health professionals

• 6 core process collapsed into 3 dimensions – openness, awareness and engagement

• ACT stance: relationship is equal, caring, and respectful

• Pain management means shifting focus from experiences that are trying to eliminate e.g. pain, towards experiences that wanting to increase e.g. achievement of goals
PACT Sessions

PACT Session 1: face to face
1. Assessment, feedback and rationale
2. Shifting focus
3. Values based goal setting
4. Address barriers

PACT Session 2: face to face, 2 weeks later
1. Review successes and challenges
2. Goal adjustment
3. Prepare for self-management

PACT Booster Call: 20 minute phone call at 1 month
PACT compared to treatment as usual

Similarities:

- Physiotherapy assessment and exercises
- Same amount of time and attention

Differences:

- See patients for 1 hour in private
- Incorporate ACT stance and methods
- 2 days training and manual provided
Can it be done?

Feasibility study used to estimate important parameters needed to design main trial

1. Is PACT acceptable to patients?

2. Is PACT feasible - can physiotherapists be trained to deliver an ACT-based treatment?

3. Assess number of eligible participants, willingness to be randomised and sample size for trial
PACT feasibility study

- Trained one experienced physiotherapist to deliver PACT

- 10 participants with non-specific low back pain referred for physiotherapy recruited from a London hospital

- Outcomes immediately post-intervention were evaluated both qualitatively and quantitatively

- Nine participants (7 female, 2 male, mean age 55) completed the intervention, with one lost to follow-up
## Participants demographic characteristics

<table>
<thead>
<tr>
<th>No.</th>
<th>Sex</th>
<th>Age</th>
<th>Education</th>
<th>Work status</th>
<th>English 1st language</th>
<th>Back pain history</th>
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<td>1</td>
<td>F</td>
<td>33</td>
<td>University level</td>
<td>Employed FT</td>
<td>No</td>
<td>3 years pain</td>
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<tr>
<td>2</td>
<td>F</td>
<td>39</td>
<td>Graduate/Professional</td>
<td>Employed PT</td>
<td>No</td>
<td>10 years pain</td>
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<td>3</td>
<td>F</td>
<td>55</td>
<td>GCSE/O levels</td>
<td>Employed FT</td>
<td>Yes</td>
<td>Chronic sciatica</td>
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<tr>
<td>4</td>
<td>F</td>
<td>63</td>
<td>NVQ</td>
<td>Retired (age)</td>
<td>Yes</td>
<td>Over 6 months pain</td>
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<td>5</td>
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<td>48</td>
<td>A levels/HNC</td>
<td>Unemployed</td>
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<td>20 years pain</td>
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<td>6</td>
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<td>Employed FT</td>
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<td>7</td>
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<td>Retired (age)</td>
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<td>9</td>
<td>F</td>
<td>66</td>
<td>No formal education</td>
<td>Retired (age)</td>
<td>Yes</td>
<td>5 years pain</td>
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</table>
Quantitative results

• Main outcome: Roland-Morris Disability score reduced from 9.4 (SD 4.2) to 6.4 (SD 4.2) p=0.05 and clinically significant

• Significant improvements in secondary outcomes: patient-specific function (p=0.008), beliefs about back pain (p=0.02), and acceptance (p=0.008)

• No significant differences reported in physical activity or pain

• 7/9 patients were very or extremely satisfied with the care & 6/9 with the outcome of treatment they received
Qualitative results

• Key themes were identified from semi-structured interviews with patients which suggested:

1. Acceptance of pain appears key step toward self-management

2. Goal-setting works best if personal and specific

3. Targeted exercises and written material are helpful

4. PACT novel intervention is acceptable to patients

5. Physiotherapists can be trained to deliver it
Quotes from participants

“There is certain pain that I shouldn’t worry about and that it’s quite normal to feel pain, and that you don’t have to stop everything and say I can’t go on with life sort of thing” (Participant 7)

“They were very disorganised goals, random thoughts...whereas in the first session here it was much more systematic, deciding very specifically what I’d do during the intervening week and therefore what I can set myself to do during the forthcoming weeks and months. So that specificity about goal-setting I found very helpful, and I don’t think I would have done it if I hadn’t had that session.” (Participant 8)

“I still from time to time get these negative thoughts, why have I got this back pain? It hasn’t completely gone away...but it’s learning to adjust to the fact it’s not necessarily something wrong, but that I can only hope it will come over time, carrying on with the exercises and treatment I’ve been given.” (Participant 3)
Quotes from physiotherapist

“It felt quite strange at first, physios want to do things and this was just like talking, takes a while to get your head round it”

“I was nervous about getting it wrong but after a few patients it did get easier........there’re still some tools I haven’t used though”

“It’s quite hard work but an hour in a quiet room makes it possible ........it did seem to go down well with patients most of the time, although some really didn’t get it”
PACT NIHR RfPB funded trial: next steps

- 240 participants randomised to PACT or UC
- Nested qualitative Study
- Process measures
- Training package development
- Fidelity checks

The PACT Study

Eccleston C, et al. *Cochrane Database of Systematic Reviews* 2009; **2**.


Cognitive behaviour therapy for hot flushes (MENOS1&2 trials):
moderators and mediators of outcome

Professor Myra Hunter, Dr Joe Chilcot and Dr Sam Norton
Focus of talk

Development
To elaborate on methodological procedures used to identify and develop theory. “Bottom up” and “Top down” examples are provided.

Feasibility and piloting
To provide an example of a feasibility study in chronic pain and reflect on the challenges identified from the patient and NHS staff perspective.

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Medical Research Council (2006)
Hot flushes and night sweats

- 60-70% women during menopause transition lasting on average 4 years (but up to 10 years), problematic for 20-25%
- Negative impact on sleep, mood and quality of life
- Exact cause unknown; rate of change of oestrogen lowers threshold for HFNS and some evidence from lab studies that stress also lowers the threshold for flushing
- Problematic for breast and prostate cancer patients
- HRT use declined since 2002-2003 when adverse long term effects publicized
- Need for effective and acceptable non-hormonal treatments
Psychological studies

• Associated with general stress and with anxiety (before menopause)
• Negative beliefs about menopause associated with behavioural avoidance and HFNS Problem rating:
  – Social anxiety/embarrassment
  – Perceived lack of control over hot flushes
  – Negative beliefs about sleep and night sweats

• CBT promising results in exploratory trials with well women (Hunter & Liao 1996) and breast cancer patients (Hunter et al 2010)
A cognitive model of hot flushes and night sweats

Information input
- Oestrogen Withdrawal
- Menopause status
- Hot flush threshold
- Triggers

Detection & attribution
- Perceived hot flush Frequency
- Selective attention
- Body focus
- Stress negative affectivity
- Mood Depression Anxiety

Cognitive appraisal
- Problem-rating
- Beliefs: Menopause Hot flushes

Behaviour
- Behavioural reactions
- Help seeking

<table>
<thead>
<tr>
<th>Stage of Model</th>
<th>Mechanism</th>
<th>Intervention component</th>
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</thead>
<tbody>
<tr>
<td>Information input</td>
<td>Raise physiological HF threshold Reduce triggers</td>
<td>Paced breathing Stress management Monitor and modify triggers</td>
</tr>
<tr>
<td>Symptom perception</td>
<td>Shift attentional focus Improve mood Increase accurate attribution of sensations</td>
<td>Paced breathing Stress management Cognitive therapy Provide information about aetiology, causes and impacts of HF/NS and menopause</td>
</tr>
<tr>
<td>Cognitive appraisal</td>
<td>Change negative automatic thoughts and beliefs about HF/NS, sleep and menopause Improve mood</td>
<td>Provide information about aetiology, causes and impacts of HF/NS and menopause Cognitive therapy Stress management</td>
</tr>
<tr>
<td>Behaviour</td>
<td>Improve relaxation skills Increase acceptance of HF/NS Increase self-efficacy in coping with HF/NS Change sleep habits</td>
<td>Paced breathing Behavioural experiments, e.g. communication and reducing avoidance Sleep hygiene</td>
</tr>
</tbody>
</table>
CBT for hot flushes and night sweats

4 x 2 hour sessions or 6 x 1.5 hours 6-10 women
Aims: To reduce the problem-rating of HFNS

- Psychoeducation about HFNS and menopause
- Monitoring HFNS, identifying precipitants
- Paced breathing for stress and HFNS
- Cognitive therapy for stress and beliefs about HFNS and menopause
- Behavioural experiments and strategies
- Focus on night sweats and sleep

Manualised, ppt presentations, CDs and homework sheets

Prime outcome: HFNS Problem-rating
Cognitive Behaviour Therapy clinical trials

- **MENOS1** RCT Group CBT with usual care for breast cancer patients with HFNS (*Mann et al Lancet Oncology* 2012)
- **MENOS2** RCT Group CBT with Self-Help CBT and usual care for well women with HFNS (*Ayers et al Menopause* 2012)
- **EVA** RCT Group CBT vs exercise, exercise plus CBT and usual care (Dutch Cancer Society) CBT (*Duijts et al J Clin Oncology* 2012)
- **MANCAN** RCT comparing guided self-help CBT with usual care for men with HFNS associated with prostate cancer treatment (*Stefanopoulou et al submitted*)

Prime outcome=HFNS Problem-rating  
Secondary HFNS Frequency  
and Sternal skin conductance
MENOS 1: RCT of Group CBT for women who have menopause symptoms following breast cancer treatment

Mann et al (2012)  

Recruitment (278)  
Screening for eligibility (101)  
Randomised N = 96  

CBT 1-6  
n = 49  

Usual care  
n = 47  

n=43 Post-treat  n=45  

n=40 6 mth  follow up n=40  

Cancer Research UK project grant  
ISRCTN13771934
MENOS 1 Results: HFNS Problem rating

Effect size 1.19

Visit

<table>
<thead>
<tr>
<th>Visit</th>
<th>TAU</th>
<th>Group CBT</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td></td>
<td></td>
</tr>
<tr>
<td>26</td>
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</tr>
</tbody>
</table>

95% CI

Hot Flush Problem Rating

Rating 4
MENOS 2 RCT of Group and Self help CBT for well women with menopause symptoms

Screened= 295
Randomised=140

Interview and Randomisation
Pre-treatment assessment

Group CBT
N=48

Post-treatment
Assessment N=46
6-8 weeks later

Follow up N=39
6 months

Self-help CBT
N=47

Post-treatment
Assessment N=40
6-8 weeks later

Follow up N=32
6 months

Control
N=45

Assessment
N=43
6-8 weeks later

Follow up N=40
6 months
Results: Primary outcome hot flush problem rating

Effect sizes: 1.18 to 1.41
Moderation

• A **moderator** is a third variable that affects the strength (or direction) of the relationship between two variables (**modifies** the effect)

• A **moderator** can make this relationship stronger or weaker, and possibly change its direction
Moderators – who does it help?

MENOS1: CBT was effective at reducing problem rating at 9 weeks regardless of: Age, BMI, time since breast cancer diagnosis, menopausal status at time of diagnosis, or type of cancer treatment (radiotherapy, chemotherapy or endocrine treatment).

The treatment effect was significantly greater:
✓ in women not receiving chemotherapy ($-2.86$, 95%CI $-4.01$ to $-1.71$, p < 0.001) compared to those who did ($-1.30$, 95% CI $-2.11$ to $-0.49$, p = 0.002),
✓ those with higher levels of psychological distress at baseline.

MENOS2: CBT was effective regardless of age, BMI, menopausal status, or psychological distress at baseline.
Those who had read the book and carried out the homework assignments benefitted more.

*Chilcot, Norton & Hunter, Maturitas 2014; Norton S, Chilcot J, Hunter MS. Menopause 2014 on line*
Mediation in RCTs

IV (treatment vs. control) → Mediator (baseline value) → Mediator (post intervention) → Outcome at follow-up

Outcome variable (baseline)
Mediators – how does group CBT work?

Significant reduction in physiological HF frequency for CBT for well women (MENOS2) but not for breast cancer patients (MENOS1) (Stefanopoulou & Hunter Menopause, 2013)

<table>
<thead>
<tr>
<th>Mediator</th>
<th>MENOS 1</th>
<th>MENOS 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Beliefs about control/coping</td>
<td>60%</td>
<td>53%</td>
</tr>
<tr>
<td>Beliefs about sleep</td>
<td>31%</td>
<td>35%</td>
</tr>
<tr>
<td>Depressed mood</td>
<td>24%</td>
<td>ns</td>
</tr>
<tr>
<td>Social context beliefs</td>
<td>29%</td>
<td>ns</td>
</tr>
</tbody>
</table>

ns: non significant although similar % accounted for
Qualitative interviews MENOS 1 and 2

- Results were consistent across MENOS 1 and 2 trials
- Improved coping (using information, paced breathing and strategies) associated with a restored sense of control
- Acceptance described as central to improved experience (staying with the hot flush symptoms, rather than avoiding)
- Women experienced beneficial changes which extended beyond their HFNS symptoms

A cognitive model of hot flushes and night sweats

Information input

- Oestrogen Withdrawal
- Menopause status
- Hot flush threshold
- Triggers

Detection & attribution

- Perceived hot flush Frequency
- Selective attention Body focus
- Stress negative affectivity

Cognitive appraisal

- Problem-rating Severity
- Control and Social beliefs Hot flushes
- Mood Depression Anxiety

Behaviour

- Behavioural reactions Help seeking

<table>
<thead>
<tr>
<th>Stage of Model</th>
<th>Mechanism</th>
<th>Intervention component</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information input</td>
<td>Raise physiological HF threshold</td>
<td>Paced breathing</td>
</tr>
<tr>
<td></td>
<td>Reduce triggers</td>
<td>Stress management</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Monitor and modify triggers</td>
</tr>
<tr>
<td>Symptom perception</td>
<td>Shift attentional focus</td>
<td>Paced breathing</td>
</tr>
<tr>
<td></td>
<td>Improve mood</td>
<td>Stress management</td>
</tr>
<tr>
<td></td>
<td>Increase accurate attribution of sensations</td>
<td>Cognitive therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Provide information about aetiology, causes and impacts of HF/NS and menopause</td>
</tr>
<tr>
<td>Cognitive appraisal</td>
<td>Change negative automatic thoughts and beliefs about HF/NS, sleep and menopause</td>
<td>Provide information about aetiology, causes and impacts of HF/NS and menopause</td>
</tr>
<tr>
<td></td>
<td>Improve mood</td>
<td>Cognitive therapy</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stress management</td>
</tr>
<tr>
<td>Behaviour</td>
<td>Improve relaxation skills</td>
<td>Paced breathing</td>
</tr>
<tr>
<td></td>
<td>Increase acceptance of HF/NS</td>
<td>Behavioural experiments, e.g. communication and reducing avoidance</td>
</tr>
<tr>
<td></td>
<td>Increase self-efficacy in coping with HF/NS</td>
<td>Sleep hygiene</td>
</tr>
<tr>
<td></td>
<td>Change sleep habits</td>
<td></td>
</tr>
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MENOS 1 and 2: Conclusions

• These results suggest that both Group and Self Help CBT may be viable alternatives to medical treatments
• Both treatments are brief, acceptable and have sustained effects
• The results generally support the model, e.g. we need to focus on these specific cognitions and the factors influencing these from the qualitative data. To investigate the role of paced breathing in experimental studies.
• Next steps - translational research and cost effective forms of the intervention.
Current trials and future directions

• Developing cCBT in an RCT with Dutch group for breast cancer patients (EVA-online), Dutch cancer Society (Aaronson, Hunter et al 2015)
• Evaluating delivery of brief CBT for HFNS in the workplace, Wellbeing of Women (Hunter & Griffiths 2015)
• Multi-centre study to evaluate delivery of training oncology nurses to deliver Group CBT (Fenlon & Hunter 2015)
• Self help book Hunter & Smith 2013
• Publishing Group CBT Manual for Health Professionals Hunter & Smith Dec 2014
• NICE guidance 2015...

Thank you
Acknowledgements

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• Alice Malpass