Development of a core set of outcome measurements for use in research evaluations of interventions used for venous leg ulceration

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Overview of the presentation

➢ Setting the scene

➢ Why are Core Outcome Sets important?

➢ Method: Scoping review

➢ Results of the scoping review

➢ Healing outcomes

➢ Next steps of the CoreVen project
Setting the scene

What is an outcome?
“*what* is being measured…In the context of a clinical trial it refers to any identified result in an outcome arising from exposure to a causal factor or a health intervention” (Prinsen et al; 2014)

Number of outcomes measured in RCT’s is so large that it is difficult to compare the results (Gethin et al; 2015) causing:

- Difficulties comparing and contrasting the outcomes of the trials
- Difficulties interpreting the results
- Makes decision making on interventions used for venous leg ulcers challenging
Why are Core Outcome Sets important?

What is a core outcome set?
- An agreed minimum set of outcomes (COMET, 2017)

Important:
- Inform clinical practice by facilitating decision making
  - Comparing, contrasting and synthesising the outcomes will be easier
  - Better understanding of the intervention being measured
- Make every trial count
Method: Scoping review

Overview:

<table>
<thead>
<tr>
<th>Broad research question(s)</th>
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<tbody>
<tr>
<td>Inclusion/exclusion developed <em>post hoc</em></td>
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<tr>
<td>Quality not a priority</td>
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<tr>
<td>Data extraction may or may not be done</td>
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<td>Identifies parameters and gaps in the literature</td>
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<td>Maps out concepts in a field of interest (Arksey and O’Malley, 2005)</td>
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<td>Rapid underpinning (Mays, Roberts and Popay, 2001)</td>
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- Five-stage process (Levac et al’s; 2010) adapted version of Arksey and O’Malleys (2005) methodological framework
Results of the scoping review

- Potentially relevant Cochrane systematic reviews n= 48
- Excluded protocols, reviews with no included trials and non-venous leg ulcer related reviews n= 23
- Cochrane systematics reviews included= 25
- Excluded RCT’s due to duplicates and non-venous leg ulcer related trials n=40
- Records of trials (including full text reports, conference abstracts, unpublished reports) n= 537
- Unable to obtain full copy of record n= 269
- Record of trials included in the scoping review n= 228

Number of potential outcomes extracted= **1165** (before de-duplication)

- Healing= **104** (post de-duplication)
Next steps of the CoreVen project

Consensus on the groups of outcomes
Bristol Online Survey:

Rate each group of outcomes using a structured rating scale

Have we missed any important groups of outcomes

Consensus on the associated outcomes
DELPHI method
Two stage Bristol Online Survey:

Rate each outcome using a structured rating scale

Have we missed any important outcomes

Systematic review

Performance of the measurement instruments

COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments, 2016) checklist
Conclusion

A core outcome set and their corresponding measurement instruments are needed in future VLUs effectiveness evaluations. It will help:

➢ Healthcare professionals
➢ Researchers
➢ Patients
➢ Carers

Easier to compare and contrast results

Reduce ‘waste’

Make every trial count
CoreVen steering group

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Thank you….

Do you have any questions?

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References


