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**LONDON**

# PREVENTion and Treatment of incontinence associated dermatitis (IAD) through optimising care: development and feasibility of the IAD Manual (PREVENT-IAD)

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# From cup of coffee to Funding

- Chat over a coffee
- Establishment of international research group for IAD (Ghent 2012)
- Pitched idea for Cochrane Review
- Co-authored Cochrane review (Beeckman et al, 2016)
- Picked up by NIHR
- HTA commissioned call August 2018
- Successful award October 2019 (£509k)
- Grant activated on 01/03/20; paused 30 days later!

# Meet the team

## KCL Team

Prof Christine Norton

Prof Ruth Harris

Dr Joanne Fitzpatrick

Trevor Murrells

Chris Chatterton

Sangeeta Sooriah

## UoS Team

Prof Mandy Fader

Prof Lisette

Schoonhoven (Utrecht)

Dr Peter Worsley

## **International Collaborators:**

Prof Dimitri Beeckman (Ghent)

Dr Jan Cottner (Berlin)

# What is IAD

- Skin damage caused by repeated contact with urine and/or faeces
- 14 million adults have urinary incontinence & 6.5 million have bowel problems in UK
- Incidence of IAD in UK is unknown but may be up to:
  - 51% at home
  - 30% nursing & residential care

# Differentiation from pressure ulcers is challenging

- Often misdiagnosed as a pressure ulcer
- Can contribute to formation of pressure ulcers





# Prevention and treatment

- Skin cleansing and application of skin protectants
- Contenance promotion
- Correct use of incontinence pads
- Odds of developing IAD may be halved with appropriate prevention
- Lack of specific guidelines for IAD management

# Research Question

Is it feasible to develop, manualise and test a package of care for the prevention and treatment of IAD that can be delivered by a range of NHS and other care givers?



# Study design

- 2 year mixed methods study over three phases

1. Evidence synthesis & development of IAD Manual + training package
2. Design definitive cluster randomised controlled trial of the IAD Manual
3. Feasibility cluster RCT

# Phase 1 – (0-12 months)

- Update our Cochrane reivew
- 4 interactive 1-day Stakeholder workshops with  
10-15 health professionals
- 10-15 residents/family carers

## Phase 2 (9-12 months)

- With same stakeholders from phase 1
- Design future cluster RCT of the IAD Manual
- Clear stop/proceed rules at this point

# Phase 3 (12-24 months)

- Feasibility Cluster RCT of the IAD Manual with nested process evaluation
- 4 large care homes
- 2 home care agencies
  - 3 to intervention & 3 to control group

# Outcomes

- Recruitment/retention rates
- Intervention fidelity (observation 3 & 6/12)
- Core outcomes for IAD (IAD severity, pain, satisfaction)
  - Used to inform power calculations

# Qualitative work

- Up to 20 residents/family and care staff will be interviewed about their experience and acceptability of the IAD Manual

# Update on the Cochrane review (Beeckman et al, 2016)

- 13 studies (prevention & treatment)
- 1316 Participants
  - Incontinent of urine/faeces/both
  - Care homes/hospitalised
- Small samples, short follow-up, high risk of bias

# Types of studies

- Comparison of different topical skin care products or combination (n=9)
- Comparison of skin care procedure (n=2)
- Comparison of products & frequency (n=1)
- Comparison of frequency (n=1)



# Main findings: skin care procedures (2 studies)

- skin cleanser might be more effective than soap and water
  - (risk ratio (RR) 0.39, 95% confidence interval (CI) 0.17 to 0.87)
- washcloth with cleansing, moisturising, and protecting properties, might be more effective than soap and water
  - (RR 0.31, 95% CI 0.12 to 0.79; moderate quality evidence)

# Main Findings: Skin care products

- All other studies – low or very low quality evidence
- Suggest that applying a leave-on product (moisturiser, skin protectant, or a combination) might be more effective than not applying a leave-on product

# 2021 Update

85 studies screened against title and abstract

53 studies excluded

32 studies assessed for full-text eligibility

10 studies excluded

4 Wrong patient population

1 Wrong intervention

1 Wrong study design

4 studies ongoing

16 studies awaiting classification (Chinese)

6 studies included

# 6 New study reports included of 4 studies

Behairy et al 2015

Cooper et al 2008

Coyer et al 2017/2020

Gaspar 2016/12018

# Study findings: Behairy et al 2015 – Saudi Arabia - hospital

- Quasi-experimental design-convenience sample =60 (attrition n=20)
- Randomised to skin intervention protocol v standard care
- Significant difference by day 4-7 in favour of intervention ( $p=0.014$ )

# Study findings: Cooper et al 2008 UK- c/o elderly wards

- Cluster randomised
- Compared Tena Wash Mousse (n=13) or Clinisan Foam Cleanser (n=14)
- No deterioration in either group

# Study Findings: Coyer 2017/2020- Australia ITU

- 36 participants randomised (pilot study)
- Cavillon advanced skin protectant + no rinse pH neutral skin cleanser v standard care (no rinse pH neutral skin cleanser + dimethicone impregnated wipe).
- 2 pts in intervention (11%) v 3 in control group develop IAD
- Challenges with recruitment

# Study Findings: Gaspar 2016/2018 –Spain - hospital

- 180 acutely ill older people randomised
- Structured IAD prevention protocol (gentle cleansing/moisturiser/zinc oxide barrier) 3/7 v standard care
- lower incidence of IAD ( $\chi^2=22.160$ ,  $p=0.000$ )



# Where are we now?

- Recommenced November 2020
- Phase 1 almost complete – thanks to all our stakeholders!
- Delays with ethics (COVID prioritised)
- Writing up prevention Cochrane review

# And where do we go from here?

- Screening and data extraction for treatment systematic review
- Ethical approval for phase 3 (IRAS)
- Finalise “manual” & training plan
- Recruit care homes and home care agencies
- Aim to complete by June 2023

# References

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