OCR
Oxford Cambridge and RSA

Wednesday 5 June 2019 – Morning

LEVEL 3 CAMBRIDGE TECHNICAL IN HEALTH AND SOCIAL CARE

05871 Unit 25: Research methods in health, social care and childcare

Pre-release material

Please write clearly in black ink.

Centre number | | | | | | Candidate number | | | | |

First name(s) _____

Last name _____

Date of Birth | D | D | M | M | Y | Y | Y | Y |

GUIDANCE NOTES

- This pre-release material contains three research articles on three different themes.
- The question paper will require learners to respond to questions about research they have completed and questions which are associated with general research principles.
- Learners need to conduct research linked to the pre-release material in the five weeks they have access to the document.

INSTRUCTIONS FOR TEACHERS

- This material must be issued 6 weeks prior to the published examination date.
- This material must be printed on A4 only.
- Learners are permitted to summarise their research findings and record results/evidence/data gathered **in the notes pages at the back of this document only** (not in the margins or around the pre-release material itself or on additional sheets) and **must not exceed the 2 pages provided**.
- The notes section must **not** be used to produce a formal write-up of the research conducted.
- Teachers must collect in each learner's pre-release material and notes **one calendar week** prior to the exam date.
- Teachers must check that the notes made are appropriate and are the learners' own work in advance of the examination taking place.
- The pre-release and notes must then be returned to learners **immediately before the exam** commences.
- The pre-release and notes **must** be submitted along with the learners' Question Paper at the end of the examination.

INFORMATION FOR LEARNERS

- You **must** choose one of the research articles (source **A**, **B** or **C**).
- You **must** identify a specific focus from the article for further secondary research.
- You **must** then complete further secondary research related to your focus, using **at least two** sources.
- Your notes on the research **must not** exceed the pages provided in this document; no additional sheets may be taken into the examination.
- Your secondary sources **must be** recorded on page 6 of this document.
- Notes are only permitted on pages 7 and 8, not elsewhere within the pre-release material such as in the margins or around the sources themselves.
- You **must** hand in your pre-release material and notes with your question paper at the end of the examination.

SOURCE A

Summary of: AAV5–Factor VIII Gene Transfer in Severe Hemophilia A

Savita Rangarajan, M.B. B.S., Liron Walsh, M.D., Will Lester, M.B., Ch.B., Ph.D., David Perry, M.D., Ph.D., Bella Madan, M.D., Michael Laffan, D.M., Hua Yu, Ph.D., Christian Vettermann, Ph.D., Glenn F. Pierce, M.D., Ph.D., Wing Y. Wong, M.D., and K. John Pasi, M.B., Ch.B., Ph.D.

Background

Patients with hemophilia A rely on exogenous factor VIII to prevent bleeding in joints, soft tissue, and the central nervous system. Although successful gene transfer has been reported in patients with hemophilia B, the large size of the factor VIII coding region has precluded improved outcomes with gene therapy in patients with hemophilia A.

Methods

We infused a single intravenous dose of a codon-optimized adeno-associated virus serotype 5 (AAV5) vector encoding a B-domain–deleted human factor VIII (AAV5-hFVIII-SQ) in nine men with severe hemophilia A. Participants were enrolled sequentially into one of three dose cohorts (low dose [one participant], intermediate dose [one participant], and high dose [seven participants]) and were followed through 52 weeks.

Results

Factor VIII activity levels remained at 3 IU or less per deciliter in the recipients of the low or intermediate dose. In the high-dose cohort, the factor VIII activity level was more than 5 IU per deciliter between weeks 2 and 9 after gene transfer in all seven participants, and the level in six participants increased to a normal value (>50 IU per deciliter) that was maintained at 1 year after receipt of the dose. In the high-dose cohort, the median annualized bleeding rate among participants who had previously received prophylactic therapy decreased from 16 events before the study to 1 event after gene transfer, and factor VIII use for participant-reported bleeding ceased in all the participants in this cohort by week 22.

Conclusions

The infusion of AAV5-hFVIII-SQ was associated with the sustained normalization of factor VIII activity level over a period of 1 year in six of seven participants who received a high dose, with stabilization of hemostasis and a profound reduction in factor VIII use in all seven participants. In this small study, no safety events were noted, but no safety conclusions can be drawn.

SOURCE B

Summary of:

The Daily Mile makes primary school children more active, less sedentary and improves their fitness and body composition: a quasi-experimental pilot study Ross A. Chesham, Josephine N. Booth, Emma L. Sweeney, Gemma C. Ryde, Trish Gorely, Naomi E. Brooks and Colin N. Moran *BMC Medicine* 2018 16:64.

Background

The Daily Mile is a physical activity programme made popular by a school in Stirling, Scotland. It is promoted by the Scottish Government and is growing in popularity nationally and internationally. The aim is that each day, during class time, pupils run or walk outside for 15 min (~1 mile) at a self-selected pace. It is anecdotally reported to have a number of physiological benefits including increased physical activity, reduced sedentary behaviour, increased fitness and improved body composition. This study aimed to investigate these reports.

Methods

We conducted a quasi-experimental repeated measures pilot study in two primary schools in the Stirling Council area: one school with, and one without, intention to introduce the Daily Mile. Pupils at the control school followed their usual curriculum. Of the 504 children attending the schools, 391 children in primary classes 1–7 (age 4–12 years) at the baseline assessment took part. The follow-up assessment was in the same academic year. Outcomes were accelerometer-assessed average daily moderate to vigorous intensity physical activity (MVPA) and average daily sedentary behaviour, 20-m shuttle run fitness test performance and adiposity assessed by the sum of skinfolds at four sites. Valid data at both time points were collected for 118, 118, 357 and 327 children, respectively, for each outcome.

Results

After correction for age and gender, significant improvements were observed in the intervention school relative to the control school for MVPA, sedentary time, fitness and body composition. For MVPA, a relative increase of 9.1 min per day (95% confidence interval or 95%CI 5.1–13.2 min, standardised mean difference SMD = 0.407, p = 0.027) was observed. For sedentary time, there was a relative decrease of 18.2 min per day (10.7–25.7 min, SMD = 0.437, p = 0.017). For the shuttle run, there was a relative increase of 39.1 m (21.9–56.3, SMD = 0.236, p = 0.037). For the skinfolds, there was a relative decrease of 1.4 mm (0.8–2.0 mm, SMD = 0.246, p = 0.036). Similar results were obtained when a correction for socioeconomic groupings was included.

Conclusions

The findings show that in primary school children, the Daily Mile intervention is effective at increasing levels of MVPA, reducing sedentary time, increasing physical fitness and improving body composition. These findings have relevance for teachers, policymakers, public health practitioners, and health researchers.

SOURCE C

Summary of:

Impact of person-centred care training and person-centred activities on quality of life, agitation, and antipsychotic use in people with dementia living in nursing homes: A cluster-randomised controlled trial Clive Ballard, Anne Corbett, Martin Orrell, Gareth Williams, Esme Moniz-Cook, Renee Romeo, Bob Woods, Lucy Garrod, Ingelin Testad, Barbara Woodward-Carlton, Jennifer Wenborn, Martin Knapp, Jane Fossey, LPOS, Feb 6th 2018.

Background

Agitation is a common, challenging symptom affecting large numbers of people with dementia and impacting on quality of life (QoL). There is an urgent need for evidence-based, cost-effective psychosocial interventions to improve these outcomes, particularly in the absence of safe, effective pharmacological therapies. This study aimed to evaluate the efficacy of a person-centred care and psychosocial intervention incorporating an antipsychotic review, WHELD, on QoL, agitation, and antipsychotic use in people with dementia living in nursing homes, and to determine its cost.

Methods and findings

This was a randomised controlled cluster trial conducted between 1 January 2013 and 30 September 2015 that compared the WHELD intervention with treatment as usual (TAU) in people with dementia living in 69 UK nursing homes, using an intention to treat analysis. All nursing homes allocated to the intervention received staff training in person-centred care and social interaction and education regarding antipsychotic medications (antipsychotic review), followed by ongoing delivery through a care staff champion model. The primary outcome measure was QoL (DEMQOL-Proxy). In all, 847 people were randomised to WHELD or TAU, of whom 553 completed the 9-month randomised controlled trial. The intervention conferred a statistically significant improvement in QoL (DEMQOL-Proxy Z score 2.82, $p = 0.0042$; mean difference 2.54, SEM 0.88; 95% CI 0.81, 4.28; Cohen's D effect size 0.24). There were also statistically significant benefits in agitation (CMAI Z score 2.68, $p = 0.0076$; mean difference 4.27, SEM 1.59; 95% CI −7.39, −1.15; Cohen's D 0.23) and overall neuropsychiatric symptoms (NPI-NH Zscore 3.52, $p < 0.001$; mean difference 4.55, SEM 1.28; 95% CI −7.07,−2.02; Cohen's D 0.30). Benefits were greatest in people with moderately severe dementia. There were no statistically significant differences between WHELD and TAU for the other outcomes. A sensitivity analysis using a pre-specified imputation model confirmed statistically significant benefits in DEMQOL-Proxy, CMAI, and NPI-NH outcomes with the WHELD intervention. Antipsychotic drug use was at a low stable level in both treatment groups, and the intervention did not reduce use. The WHELD intervention reduced cost compared to TAU, and the benefits achieved were therefore associated with a cost saving. The main limitation was that antipsychotic review was based on augmenting processes within care homes to trigger medical review and did not in this study involve proactive primary care education. An additional limitation was the inherent challenge of assessing QoL in this patient group.

Conclusions

These findings suggest that the WHELD intervention confers benefits in terms of QoL, agitation, and neuropsychiatric symptoms, albeit with relatively small effect sizes, as well as cost saving in a model that can readily be implemented in nursing homes. Future work should consider how to facilitate sustainability of the intervention in this setting.

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