

Background/aims We developed a novel, long-term condition-specific Interactive Health Communication Application, the on-line parent information and support (OPIS) to promote parents' home-based management ability. We aimed to assess feasibility of a future full-scale randomised clinical trial (RCT) of OPIS in terms of recruitment, retention and data collection procedures; and investigate trends in change on outcomes in a small-scale preliminary RCT in parents.

Methods Parents were randomly assigned to: usual support (control) or usual support plus OPIS access for 20 weeks (intervention). Both groups completed study measures at study entry (T1) and exit (T2). We assessed feasibility between groups.

Results 55 parents of 39 children enrolled in the RCT; 19/26 (73%) of intervention parents and 22/29 (76%) of control parents completed T2 data collection. The overall retention rate was 41/55 (75%). Data collection was judged to be feasible. All intervention parents showed evidence of having accessed OPIS, indicating complete uptake. The intent-to-treat analysis showed greater improvement in self-efficacy to manage their child's condition for intervention parents when compared to control group parents (3.21 v 1.09, 95% CI -1.27 to 5.51, Cohen's d = .41).

Conclusion A full-scale RCT of OPIS is feasible. OPIS has the potential to beneficially affect self-reported outcomes including parents' competence to provide home-based clinical care-giving. A full-scale RCT that is sufficiently powered to detect the effects of OPIS on outcomes is indicated. Our design and methodology could potentially be transferred to the management of other conditions.

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EXCESSIVE GROWTH FROM 6 TO 24 MONTHS OF AGE: RESULTS FROM THE PREVENTION OF OVERWEIGHT IN INFANCY (POI) RANDOMISED CONTROLLED TRIAL

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The Prevention of Overweight in Infancy study investigated whether education and support around sleep, physical activity, and diet could reduce excessive weight gain in the first two years of life. The analysis presented here assessed weight at 24 months postpartum and growth from 6 to 24 months. 802 mother-infant pairs were randomised to: 1) FAB – food, activity and breastfeeding (8+ contacts), 2) Sleep – prevention and treatment of sleep problems (2+ contacts), 3) Combo – both interventions (10+ contacts), or 4) Control. All groups received standard government funded “Well Child” care (7 contacts). Anthropometric measurements were obtained at 6, 12, 18 and 24 months postpartum by trained measurers blinded to group allocation. Rapid and extremely rapid growth were defined as a change in BMI z-score > 2/3 SD (World Health Organisation definition) and > 4/3 SD respectively. 84.5% (n = 678/802) of participants were followed up at 24 months with 40.1% having BMIs ≥ 85th percentile (n = 272). Among those with both 6 and 24 month data, 53.9% (351/651) showed rapid growth with 148 of these showing extremely rapid growth (22.7% of the sample). There was no difference between intervention groups for rapid growth

(p = 0.892) or extremely rapid growth (p = 0.630) compared to normal growth. Similarly, there was no intervention effect on those classified as overweight at 24 months who also displayed rapid or extremely rapid growth (p = 0.936 for rapid growth, p = 0.485 for excessive rapid growth) from 6–24 months. Our results indicate it is difficult to modify excessive growth.

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SAFEBOOSC – A PHASE II RANDOMISED CLINICAL TRIAL ON CEREBRAL NEAR-INFRARED SPECTROSCOPY OXIMETRY IN EXTREMELY PRETERM INFANTS

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Background and aims Extremely preterm infants have a high risk of moderate to severe long-term neurodevelopmental impairment. Hypoxic or hyperoxic brain injury may be a contributing factor. The SafeBoosC trial investigated if it is possible to stabilise the cerebral oxygenation of extremely preterm infants.

Methods This was a phase II randomised, single blinded, clinical trial. Infants born before 28 weeks of gestation were eligible. Within 3 h of birth, infants were randomly assigned to either cerebral near infrared spectroscopy (NIRS) oxygenation monitoring in combination with a treatment guideline (experimental) or blinded NIRS monitoring with standard care (control). The primary outcome was the area under the curve of the time series of absolute deviation from the cerebral oxygenation target range of 55% to 85%, expressed in % hours (the burden of hypoxia and hyperoxia). We hypothesised that there would be more than 50% reduction in this burden in the experimental group.

Results 166 infants with a median postmenstrual age of 26.4 weeks were enrolled (Table 1). Two infants were withdrawn. 86 infants randomised to the NIRS group had a median burden of hypoxia and hyperoxia of 36.1% hours (IQR 9.2 to 79.5)

Abstract O-221 Table 1

Characteristics	Experimental (n = 86)	Control (n = 80)
Birth weight, median (range), g.	806 (410 to 1286)	880 (490 to 1330)
Gestational age at birth, median (IQR), wk.	26.6 (25.7 to 27.4)	26.8 (25.5 to 27.6)
Male sex, n (%)	44 (51.2)	34 (42.5)
Multiple births, n (%)	20 (23.3)	14 (17.5)
Prenatal steroids, n (%)	58 (67.4)	56 (70.9)
Prolonged rupture of membranes, n (%)	26 (30.6)	32 (40.5)
Maternal clinical chorioamnionitis, n (%)	6 (7.1)	7 (9.0)
Apgar score ≤ 5 at 5 min, n (%)	15 (17.6)	14 (17.7)
Umbilical arterial pH, mean (SD)	7.33 (0.088)	7.31 (0.096)

compared with 81.3% hours (IQR 38.5 to 181.3) in the control group (Figure 1), a reduction of 58% (95% CI 35% to 73%) ($p = <0.0001$). We found no other statistically significant differences between the two groups to term corrected age.

Conclusions Cerebral oxygenation was stabilised using a treatment guideline in combination with cerebral NIRS monitoring in extremely preterm infants.

0-222 EVALUATION OF THE INFLUENCE OF BIFIDOBACTERIUM LACTIS 2011 AND HINDIBA INULIN ON FEEDING INTOLERANCE AND NECROTISING ENTEROCOLITIS IN PREMATURE BABIES

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Aim To evaluate the influence of bifidobacterium lactis 2011 and hindiba inulin on feeding intolerance and necrotising enterocolitis in premature babies

Material and method 89 premature babies with the diagnosis of feeding intolerance were enrolled in the study. Premature babies were divided into two groups; Study group (group 1) had Bifidobacterium Lactis (5×10^9 CFU) + Hindiba Inulin (900 mg) (Maflor^R) liquefied with 10 ml sterile water with the dosage of 3×1 ml peroral while control group (group 2) did not have any medication for feeding intolerance.

Results Gender and gestational weeks of the groups were not significantly different. B. Lactis vs Hindiba Inulin was started at mean 9.9 days and continued for mean 11.1 days. Time of starting oral feeding and time of full enteral feeding were longer in study group and this was statistically significant. ($p < 0,05$). Although NEC was not significantly different between groups ($p > 0,05$), babies in the study group diagnosed as in Grade 1 and did not progress, one third of the diagnosed babies in the control group progressed to Grade 2. When the groups were compared according to weight gain, study group gained more weights and it was statistically significant. ($p < 0,05$).

Conclusion Probiotics and prebiotics may have positive effect due to higher weight gain and not advancing in NEC in study group having B. Lactis and Hindiba Inulin.

0-223 THE VICI-TRIAL: AN INTERNATIONAL MULTICENTER RANDOMISED CLINICAL TRIAL COMPARING HFO AND CMV AS INITIAL VENTILATION STRATEGY IN CONGENITAL DIAPHRAGMATIC HERNIA

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Background Congenital diaphragmatic hernia (CDH) is a life-threatening anomaly with significant mortality and morbidity. The

Abstract 0-223 Table 1

Variables: corrected for centre			
(results are presented as n (%) or median (IQR)	HFO (n = 80)	CMV (n = 91)	p-value
Length of ventilation (days)	13 (8–23)	10 (6–18)	0.03
Severity CLD			
No CLD	37 (46.3%)	50 (54.9%)	
Mild CLD	7 (8.8%)	13 (14.3%)	
Moderate CLD	2 (2.5%)	1 (1.1%)	
Severe CLD	9 (11.3%)	6 (6.6%)	
Died	25 (31.3%)	21 (23.1%)	0.13
ECMO (in ECMO centres only)	24 (51.1%)	16 (26.2%)	0.007
Inhaled nitric oxide	45 (56.3%)	39 (42.9%)	0.045
Sildenafil	25 (31.3%)	11 (12.1%)	0.004
Inotropics	73 (91.3%)	73 (80.2%)	0.08
Duration inotropics (days)			
(in survivors only)	8 (4.25- 19)	6 (3.25- 11.75)	0.02

lungs have a high susceptibility for oxygen and ventilation damage resulting in a high incidence of chronic lung disease (CLD).

Aim To establish the optimal initial ventilation strategy in CDH.

Methods In a prospective, randomised international multicenter trial initiated by the CDH Euroconsortium (VICI-trial, NTR 1310), prenatally diagnosed CDH neonates born between November 2008 and December 2013, were randomised for either conventional mechanical ventilation (CMV) or high-frequency oscillation ventilation (HFO) as initial ventilation mode. Primary outcome measure was death or CLD (Jobe and Bancalari, 2001) at day 28 analysed by multiple logistic regression analysis corrected for centre, lung-to-head ratio, liver position and side of defect. Secondary outcome was corrected for centre.

Results Of the 171 included patients, 91 (53.2%) initially received CMV (median gestational age 38.1 weeks) and 80 (46.8%) HFO (median gestational age 38.0 weeks). In total, 21 (23.1%) patients ventilated by CMV died and 25 (31.3%) in HFO. Of the survivors, 21 (23.1%) had CLD in CMV and 18 (22.5%) in HFO. Primary outcome measure showed that in CMV 41 (45.1%) died or had CLD at day 28 and in HFO 43 (53.8%), OR 0.6, 95% CI [0.12–2.54]. Results of secondary outcome are shown in Table 1.

Conclusions Although the primary outcome was statistically not significant, CDH patients initially ventilated by CMV were ventilated less days, received inotropics less days, and received less often nitric oxide, sildenafil and ECMO compared to HFO.

0-224 TOLL-LIKE RECEPTORS GENOTYPE POLYMORPHISM IN EGYPTIAN CHILDREN WITH CHRONIC VIRAL HEPATITIS C

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Background Toll-like receptors (TLRs) are important molecules for both innate and adaptive immune responses. The prevalence of TLRs polymorphism varies in different populations and controversial results were reported in HCV patients. We aimed to assess the frequency of TLR2 Arg753Gln, TLR4 Asp294Gly and TLR4 Thr399Ile polymorphisms among Egyptian children with chronic HCV and to study their relation to clinical data.

Methods An observational case control study was conducted in Mansoura University Children's Hospital, Egypt and included