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The impact of low-energy, partially hydrolysed enteral formula on gastrointestinal symptoms and weight in children with neurological impairment: a multicentre retrospective study

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Abstract

Background: Neurological impairment (NI) relates to disorders of the central nervous system. The specific aetiology of NI varies but includes genetic, congenital abnormalities or brain injury. In children with severe NI, feeding impairments can lead to undernutrition, and some children require a feeding tube. Although tube feeding improves overall nutritional status, it has also been associated with excess body fat. Commercially available enteral formulas that are low in energy, hydrolysed and nutritionally adequate for protein and micronutrients are available to mitigate gastrointestinal symptoms and obesity.
Methods: This is a retrospective multicentre study of children who attended NI clinics between January 2022 and July 2023. Data were collected before and 1 month after receiving a low-energy, partially hydrolysed enteral formula (0.6 kcal/mL) on demographic data (age, sex, ethnicity and NI diagnosis), anthropometric measurements (weight, height, weight-for-age *Z*-score, height-for-age *Z*-score, body mass index [BMI] *Z*-score) and feed regimen (feed volume, total fluids and type of formula/supplements).
Results: Dietitians collected data on 28 children, the median age was 7 years (interquartile range [IQR] 3, 8). The most frequently recorded NI was cerebral palsy, in 13 of 28 children (48%). Before the formula switch, the most frequently reported gastrointestinal symptom was constipation, in 13 of 28 children. Within 1 month of switching to a low-energy, hydrolysed formula, 10 of the 13 (77%) children reported an improvement in constipation. Before the formula switch, all 28 children were experiencing excessive weight gain. After the formula was switched to low-energy, hydrolysed formula, dietitians reported that 20 of the 28 (76%) children's weight either stabilised or reduced after 1 month. There was no statistically significant difference in weight-for-age *Z*-score or BMI *Z*-scores postswitch of formula (p-value 0.1 and 0.09, respectively). Fibre intake increased significantly from 3.3 to 8.1 g/day ($p\text{-value} < 0.01$) after formula switch. The number of children whose feed regimens were simplified after switching to a low-energy, partially hydrolysed formula was 24 of 28 (91%).
Conclusions: Children with an NI who have gastrointestinal symptoms may benefit from a low-energy, hydrolysed enteral formula to maximise feed tolerance and promote healthy weight gain. In addition, changing to a low-energy, hydrolysed formula may simplify feed regimens by eliminating the need for additional electrolytes, multivitamins and fluid boluses. Healthcare

professionals should be knowledgeable about the effectiveness and availability of a low-energy, hydrolysed formula.

KEYWORDS

children, enteral nutrition, low-energy enteral formula, neurological impairment, nutritional support

Highlights

- A low-energy, partially hydrolysed enteral formula may promote weight stabilisation and optimise feed tolerance in tube-fed children with an NI.
- Switching to a low-energy, partially hydrolysed enteral formula may simplify overly complicated feed regimens in tube-fed children with an NI by excluding the need for additional multivitamins or electrolytes.
- Healthcare professionals should be knowledgeable about the availability of low-energy, hydrolysed formulas.

INTRODUCTION

Neurological impairment (NI) relates to disorders of the central nervous system, affecting speech, motor skills, vision, memory, muscle actions and learning abilities.[1] The specific causes of NI vary but can include genetic disorders, congenital abnormalities or brain injury. Cerebral palsy (CP) is considered a major subgroup of NI.[2] Birth prevalence of CP in high-income countries is decreasing, currently at 1.6 per 1000 live births.[3] Declines are being attributed to an array of clinical improvements in public health, maternal and perinatal care, particularly for infants cared for in a neonatal intensive care unit who are at the highest risk of CP.[4,5] CP presents a significant disease burden for the child and family in relation to feeding, mobility and psychosocial interaction.[6]

Children with severe forms of CP can be significantly disadvantaged in their ability to nourish themselves due to poor hand-to-mouth motor coordination, along with disordered swallowing, resulting in aspiration of food into the lungs.[7] The Gross Motor Function Classification System (GMFCS) is based on the everyday functional performance of children with CP including sitting, transfers and mobility. The GMFCS is based on a five-level classification, where level I represents less impairment, and level V represents severe impairment.[8] Dysphagia typically presents as feeding difficulties, extended feeding times, malnutrition and/or a history of aspiration pneumonia – symptoms considerably increase in children with severe forms of CP (GMFCS IV and V).[8] Instead of mealtimes being an enjoyable experience, they are distressing for both the child and carer.[9] These impairments in feeding eventually lead to undernutrition, and children may require a feeding tube to ensure nutritional requirements are met.[10] Gastrostomy insertion rates have been increasing in England over the past 19 years, from 3.7 to 18.3 procedures per 100,000 children under the age of 15 years, with no parallel increase in CP prevalence.[11]

Children with severe CP are prone to a positive energy balance associated with reduced energy expenditure and both high body fat mass and low muscle mass. Although tube feeding improves overall nutritional status, it has also been associated with excess deposition of body fat compared with typically developing children.[12] Children with CP are at risk of becoming overweight because of their functional and psychosocial constraints, especially those in GMFCS IV and V.[13] Additionally, nutritional, neurological and endocrine factors all contribute to sub-optimal growth.[14] Children are more likely to be overweight and tend to have low lean muscle mass; therefore, a low body mass index (BMI) in this group does not necessarily imply low-fat stores.[15] Efforts are needed to protect children with NI from overfeeding and to help families manage their children's weight.[16]

It has been reported that some children with NI who are fed up to 80% of their estimated average energy requirements (The Scientific Advisory Committee on Nutrition report on the DRVs for energy, 2011) have a positive energy balance, resulting in high body fat mass.[12] In an attempt to control excess weight gain, dietitians may dilute the existing enteral formula to a level commensurate with the energy expenditure of a child with CP in GMFCS IV and V, which has an adverse impact on micronutrient and protein intake.[12] Furthermore, gastrointestinal and nutritional problems in children with NI have been recognised as an integral part of their disease.[17] Feed tolerance is generally worse in children with NI, associated with posture and tone disorders as well as side effects of medications.[18] Common feed-related symptoms associated with NI include gastrointestinal dysmotility (vomiting, retching, constipation and loose stools) and pain associated with feeding (feed-induced dystonia).[19]

The clinical nutrition industry has responded to the complex nutritional needs of children with an NI and developed commercially available enteral formulas that are low in energy but remain nutritionally adequate for protein and micronutrients, essential for the developing child who is reliant on enteral formulas to meet most or all of their nutrient needs.[12] This national multicentre retrospective study aimed to establish the impact of a low-energy, partially hydrolysed enteral formula on gastrointestinal symptoms, weight and feed regimen (feed volume, total fluids and type of formula/supplements) in children with NI.

METHODS

Patients and study design

We collected data on demographics (age, sex, ethnicity and NI diagnosis), anthropometric measurements (weight [kilogram], length [centimetre], weight-for-age *Z*-score, height-for-age *Z*-score, BMI *Z*-score) and feed regimens (feed volume, total fluids feeding route and type of formula) from children who attended an NI clinic between January 2022 and July 2023 at Tertiary Children's Hospital, London, and a district general hospital, Worcestershire United Kingdom. Ethical approval for data collection was granted by the HRA and Health and Care Research Wales (HCRW) 21/HRA/1346 on 13 April 2021.

A multicentre retrospective review over 1 month of children who switched to Peptamen Junior 0.6 (Nestlé Health Science), a nutritionally complete low-energy (0.6 kcal per 1 mL), partially hydrolysed peptide-based whey protein, containing 0.8 g fibre per 100 mL and 35% of total fat as medium-chain triglycerides. All eligible children were aged between 1 and 17 years and had an NI diagnosis. Children's enteral tube formula must have accounted for at least 80% of their total energy requirements with at least one reported gastrointestinal symptom (gastro-oesophageal reflux, retching, vomiting, constipation and/or loose stools). Exclusion criteria were children who were receiving more than 20% of total energy intake from solid foods or had no reported gastrointestinal symptoms.

The primary outcome measure was gastrointestinal symptoms after the formula was changed to a low-energy, partially hydrolysed formula. Secondary outcomes included changes in weight (kilogram) and feed regimen (feed volume, total fluids and type of formula/supplements).

The data collected by paediatric dietitians from dietetic and medical records were inputted into a Microsoft form. Once the Microsoft forms were completed by the dietitian, forms were automatically sent to Ixia Clinical Limited. Data were compiled to represent all sites and downloaded into an Excel sheet for analysis performed by an independent statistician.

Gastrointestinal symptoms

Dietetic documentation on gastrointestinal tolerance after the feed was switched to a low-energy, hydrolysed formula was measured as either improved, no change or worsened on key markers of tolerance (gastro-oesophageal reflux, retching, vomiting, constipation and loose stools). Constipation was defined by Rome IV criteria as fewer than three defecations a week and painful and hard stools.[20] Loose stool was defined as more than one loose stool a day lasting longer than 7 days.[21] Stool form scales are a standardised and inexpensive method of classifying stools into a finite number of categories that can be used by families and healthcare professionals. The Bristol Stool Scale is a visual stool form scale; the ideal stool is generally type 3 or 4 and easy to pass without being too watery. Types 1 and 2 indicate constipation, whereas types 6 and 7 indicate loose stools.[22] Reflux was defined as the parental observation of the passage of gastric contents into the oesophagus, causing regurgitation, posseting or vomiting, which leads to troublesome symptoms that affect daily functioning.[23]

Feed regimen

Dietetic documentation on the overall impact on the enteral feeding regimen was measured as either simplified or no change after switching to a low-energy, hydrolysed formula. This evaluation of simplification of the feeding regimen was in relation to the hydration regimen (frequency of fluid boluses and fluid volumes) or the need for additional supplementation (multivitamin powder/oral hydration solution) added to the formula.

Anthropometric measurements

Weight was determined to the nearest 0.1 kg, with subjects dressed in light clothing, using a Model 880 electronic wheelchair scale (Seca). Supine length was measured to the nearest 0.1 cm without socks or shoes, using a Model 206 stadiometer (Seca). The height and weight were then used to calculate age- and gender-specific BMI (kg/m^2). These were compared with the reference population to calculate weight-for-age *Z*-scores, height-for-age *Z*-score and BMI *Z*-score[24] using UK reference curves.[25] Moderate overweight was identified if the weight-for-age *Z*-score was between +2 and +3 standard deviation (SD), and severe overweight was identified if the weight-for-age *Z*-score was > +3 SD.[26]

Statistical analysis

Parametric tests and the mean (±SD) were used for normally distributed data, and a nonparametric test with median and interquartile range (IQR) was employed for nonnormally distributed data. Descriptive statistics to measure the change in subject anthropometric characteristics and nutritional intake were tested for significance using two-sided paired *t*-tests. A p-value < 0.05 was deemed statistically significant. Statistical analysis was performed with SPSS software (version 23; IBM SPSS Statistics).

RESULTS

Data were collected on 28 children in this multicentre retrospective study; no children were excluded based on inclusion criteria. The median age of children who had switched to a low-energy, partially hydrolysed enteral formula was 7 years (IQR: 3, 8), and 12 of 28 children (41%) were female. The most frequently recorded NI of children who had switched to the new enteral formula was CP, observed in 13 of 28 children (48%). Two-thirds of the children (67%) were on a whole protein formula before switching to a low-energy, partially hydrolysed formula (Table 1). The primary mode of nutrition delivery was via a gastrostomy feeding tube in 26 of 28 children (96%), with 2 children being fed via a jejunostomy.

TABLE 1 Demographic, neurological impairment diagnosis and feeding characteristics of study participants.

Characteristic	
Gender, *n* (%)	
Female	12 (41%)
Male	16 (59%)
Age, years, median (IQR)	7.3 (3, 8)
Weight, kg, median (IQR)	24 (13, 34)
Height, cm, median (IQR)	112.5 (92, 120)
Ethnicity, *n* (%)	
Asian or Asian British	13 (47%)
White or White British	10 (35%)
Middle Eastern	3 (12%)
Black British African	2 (6%)
Neurological diagnosis, *n* (%)	
Cerebral palsy	13 (48%)
Mitochondrial disease	10 (35%)
Seizure related	5 (17%)
Feed formula before switch, *n* (%)	
Whole protein (1 kcal/mL)	19(67%)
Hydrolysed protein (1 kcal/mL)	6 (22%)
Amino acid based (1 kcal/mL)	3 (11%)
Feeding route, *n* (%)	
Gastrostomy	26 (92)
Jejunostomy	2 (8)

Abbreviation: IQR, interquartile range.

Nutritional intake

The median total feed volume significantly increased after the formula was changed to a low-energy, partially hydrolysed formula from 833 to 1017 mL (*p*-value: 0.04); however, there was no statistically significant change in the median total fluid intake before and after formula change at 1250 and 1200 mL, respectively (*p*-value: 0.6) (Table 2). The mean fat and carbohydrate intake significantly decreased after the formula was changed, but the protein intake remained the same. Fibre intake increased significantly from 3.3 to 8.1 g/day (*p*-value < 0.01) after formula changed. Vitamin A and vitamin D significantly increased after the formula was changed (Table 2).

Dietetic reasons for switching to a low-energy, partially hydrolysed formula

Excessive weight gain

Before the formula was changed, all 28 children were experiencing excessive weight gain on their current feeding regimen. The baseline mean weight-for-age *Z*-score and BMI *Z*-scores were bordering the moderate overweight category at 1.38 (95% confidence interval [CI] -0.76, 2.3) and 1.93 (95% CI −0.95, 2.4), respectively. Twenty-four children's feed regimens had been manipulated by the dietitian in a bid to stabilise weight gain by reducing total energy intake. After the formula was switched to low-energy, hydrolysed formula, dietitians

TABLE 2 Nutritional intake before and after enteral tube formula was changed to a low-energy, partially hydrolysed formula.

Nutrient	Before feed change	After feed change	*p*-Value
Feed volume, mL (IQR)	833 (700,950)	1017 (800, 1300)	0.04
Total fluid intake	1250 (950,1300)	1200 (900–1270)	0.6
Energy, kcal (SD)	833 (75)	610 (63)	<0.01
Carbohydrate	90.4 (11)	68.2 (9)	<0.01
Fat, g (SD)	41.3 (7)	25.0 (4)	<0.01
Protein, g (SD)	23.2 (6)	23.4 (6)	0.6
Sodium, mmol (SD)	21.5 (5)	23.2 (5)	0.5
Iron, mg (SD)	9.0 (1)	8.6	0.7
Calcium, mg (SD)	464 (47)	686 (53)	0.04
Vitamin A, µg (SD)	373.5 (33)	505 (45)	<0.01
Vitamin D µg (SD)	8.3 (1)	16.1 (4)	<0.01
Fibre, g (SD)	3.3 (0.4)	8.1 (1)	<0.01

Abbreviations: IQR, interquartile range; SD, standard deviation.

reported that 20 of the 28 (76%) children's weight either stabilised or reduced after 1 month. The weight-for-age *Z*-score and BMI *Z*-scores decreased to 1.30 (95% CI −0.6, 2.1) and 1.82 (95% CI −1.2, 2.9) (Table 3). There was no statistically significant difference in weight-for-age *Z*-score or BMI *Z*-score postswitch of formula (*p*-value 0.1 and 0.09, respectively).

Gastrointestinal symptoms

Before formula switch, the most frequently reported gastrointestinal symptom was constipation, observed in 13 of 28 (46%) children, followed by abdominal pain, reflux, retching and vomiting (Table 4). Within 1 month of switching to a low-energy, hydrolysed formula, 10 of the 13 (77%) children reported an improvement in constipation. Of note, fibre intake increased significantly from 3.3 to 8.1 g/day (*p*-value < 0.01) after formula switch (Table 2). Three out of three (100%) children who previously suffered from vomiting reported an improvement. Four of the five (80%) children who suffered from abdominal pain during feeding reported an improvement in postformula switch. Similarly, significant improvements were also reported in children with reflux and constipation after the formula was switched (Table 4).

The number of children whose feed regimens were simplified after switching to a low-energy, partially hydrolysed formula was 24 of 28 (91%). Of these, nine (35%) children's feeding regimens had been simplified by decreasing the number of fluid boluses. Additionally, nine (35%) children no longer required additional nutritional supplements (oral rehydration solution and/or multivitamins), whereas six (21%) children's feeding regimen had been simplified by transferring from a powder formula to 'ready to feed' formula (Table 5). An overall reduction in time dedicated to enteral feeding regimens was documented by 22 of 28 (76%) families.

TABLE 3 Anthropometric characteristics before and after enteral formula was switched to a low-energy, partially hydrolysed formula.

Anthropometric measure	Baseline	One month after feed change	*p*-Value
Weight, kg (SD)	24.81 (11.92)	24.29 (11.84)	0.7
Weight-for-age *Z*-score (95% confidence interval)	1.38 (−0.76, 2.3)	1.30 (−0.6, 2.1)	0.1
Height, cm (SD)	107 (21)	108 (20)	0.2
Height-for-age *Z*-score (95% confidence interval)	−0.85 (−1.7, 0.9)	−0.80 (0.8)	0.4
Body mass index (SD)	20.21 (4.51)	18.96 (4.49)	0.07
Body mass index *Z*-score (95% confidence interval)	1.93 (−0.95, 2.4)	1.82 (−1.2, 2.9)	0.09

Abbreviation: SD, standard deviation.

TABLE 4 Dietitians who reported an improvement in feed tolerance when children switched to low-energy, partially hydrolysed formula.

Symptom	Reported number of children with symptoms before switch, *n*	Postswitch reported improvement in symptom, *n* (%)	Other *n* (%)
Vomiting	3	3 (100%)	–
Reflux	4	3 (75%)	–
Retching	4	2 (50%)	–
Constipation	13	10 (77%)	3 (23%) No change
Abdominal pain	5	4 (80%)	1 (20%) No change

TABLE 5 Dietetic assessment on the simplification of feeding regimens and obesity risk after switching to low-energy, partially hydrolysed formula.

Clinical outcome	
Simplified feeding regimen, *n* (%)	
The hydration regimen required fewer water boluses	9 (35%)
Removal of additional supplements (oral hydration solution and/or multivitamin)	9 (35%)
Switched from powder formula to 'ready to hang' formula	6 (21%)
Reduced feeding preparation time	22 (76%)
Reduced risk of obesity, *n* (%)	
Weight gain stabilised	17 (64%)
Weight reduction	3 (12%)

DISCUSSION

Children with severe CP (GMFCS IV–V) are often unable to meet all their nutritional requirements orally and may require a feeding tube. Tube-fed children with NI can become overweight due to reduced mobility. In our study, dietitians reported that feeding a low-energy, partially hydrolysed formula improves gastrointestinal symptoms, and weight gain slowed or stabilised in line with expected growth. Furthermore, our study found that in many cases dietitians were diluting enteral formulas in a bid to mitigate excess weight gain and to meet fluid requirements, after switching formulas' feed regimens were simplified, eliminating the need for additional fluid boluses and additional supplements (oral hydration solution and multivitamins) to compensate nutrient reduction from formula dilution.

In this review, weight stabilisation or weight reduction was achieved when children switched to a low-energy, partially hydrolysed formula. Our findings support those of Vernon-Roberts et al.,[12] who investigated whether healthy weight gain could be achieved without an adverse effect on body composition by using a low-energy (whole protein) formula in gastrostomy-fed children with CP. Conclusively, children with CP who are fed a low-energy, micronutrient-complete formula continue to grow even when energy intake is below 75% of the estimated average requirements. This was not associated with a disproportionate rise in fat mass, and micronutrient intake remained within the reference range.[12]

The importance of controlling weight gain in children with an NI has been outlined by Pascoe et al.,[15] who performed a retrospective study of 587 children with CP. The team concluded that 19% of ambulant children with CP were overweight or obese, which is of concern as BMI may impact the outcomes of surgical intervention and rehabilitation.[15] Furthermore, a study by Barja et al.[27] delved deeper to explore the associated complications of obesity (dyslipidaemia and hyperinsulinemia) in children with CP. The team reported that the frequency of cardiometabolic risk factors was high in their sample of paediatric patients with CP, which was associated with overweight and low mobility. The team proposed a BMI >75th percentile as a cut-off point for metabolic risk factors.[27] However, Duran et al.[28] assessed the diagnostic performance of BMI cut-off values to identify excess body fat in children with CP and found BMI showed high specificity, but low sensitivity in children with CP. Thus, 'normal-weight obese' children were overlooked when assessing excess body fat only using BMI.[28]

An interesting and unexpected observation identified in our study was the unnecessarily complex feed regimens implemented by dietitians, who had restricted feed volume or diluted formulas in a bid to mitigate excessive weight gain while achieving the required fluid intakes. This, in turn, resulted in dietitians needing to add nutritional supplementation (oral hydration solution and multivitamins) to meet micronutrient and electrolyte requirements. To further complicate matters, the reduction in feed volume meant additional fluid blouses were incorporated to meet hydration needs. This practice from well-meaning dietitians resulted in overly complicated feed regimens being imposed on the already busy lives of parents caring for children with an NI. Implementing a low-energy formula resolved issues relating to excess weight gain without the need to dilute feed volumes, which resulted in dietitians compensating for nutritional inadequacies by adding micronutrients and electrolytes.

In this study, the micronutrient intake was maintained or increased when the formula was changed to a low-energy, partially hydrolysed formula. Meeting the micronutrient requirements of these children is a valid concern, especially when you consider the micronutrient status of wheelchair-bound children with NI in relation to bone health. Low bone mass in children with CP means increased bone fragility, and therefore, maximising peak bone mass during childhood is vital, especially when you factor in lower levels of physical activity, which further contributes to the long-term negative health consequences of poor bone mineral density.[29] Micronutrient deficiencies, specifically, calcium, iron, zinc, vitamins C, D and E and selenium, are common, especially in children who are exclusively tube-fed.[1] In this study, the protein intake was maintained after the formula was changed, which is an important observation as protein requirements for children with NI are similar to the protein requirements of neurotypical children.[1]

Additionally, the fibre intake significantly increased after the formula was changed, which may have contributed to the improvement in constipation. The current evidence supports using fibres in enteral formulas as first-line nutrition therapy. Dietary fibres should be considered for all patients receiving enteral nutrition.[30] ESPHGAN 2019 recommendation outlines the importance of using fibre-containing enteral formulas to improve bowel function, promote the growth of healthy gut microbiota, and improve immune homeostasis.[31] Regular nutritional assessment is essential and identifies signs and symptoms related to malnutrition.[1]

Our study reported that 76% of families reduced the time dedicated to feeding preparation and administration after switching formulas. This was attributed to reduced time to prepare feed recipes (20 min/day) and reduced time for additional water boluses (15 min/day). This equated to a total of 4 h savings per week (212 h per year). With an estimated cost saving of £10.80/day (£3942 per year), families of children with an NI experience increased psychological anxiety and financial problems.[32] Specifically, parents feel time pressured and struggle to maintain their social and cultural activities.[33] Although not specifically measured in this study, simplifying the feeding regimen by switching to a 'ready to feed', nutritionally complete low-energy enteral formula may have had an impact on the quality of life of families caring for children with an NI.

Limitations

The limitations of this study include its small sample size. Therefore, the results are ungeneralisable, and rather than stating causation, we can only allude to a potential association between a low-energy, partially hydrolysed enteral formula and weight stabilisation, as well as reduced associated risks of obesity. Of note, children with underlying limb or spine flexion deformities may have an inaccurate height measurement. Assessment of height reflects adequate growth and nutritional status but can be challenging in children with malformations and spasticity.[34] Other limitations include a short trial period and retrospective design. However, a strength of the study was its multicentre design, and that data gathering was from several dietitians in different clinical settings.

CONCLUSION

In summary, children with an NI who have low-energy expenditure coupled with gastrointestinal symptoms may benefit from a low-energy, partially hydrolysed enteral formula to mitigate the risk of excessive weight gain, further compromising mobility and obesogenic complications. Additionally, implementing a low-energy, hydrolysed 'ready to feed' formula may beneficially impact health economic outcomes (time-saving and financial cost) by simplifying the feed regimens. Healthcare professionals should be knowledgeable about the effectiveness and availability of low-energy, nutritionally complete formulas for tube-fed children with NI.

AUTHOR CONTRIBUTIONS

Conceptualisation and design of methodology, review and editing, data curation management of research data, final approval of the version to be published: Graeme O'Connor. *Data curation management of research data, final approval of the version to be published*: Martha Van Der Linde. *Formal analysis and application of statistics to synthesise study data*: Zoltan Hartfiel Capriles.

CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

Ethical approval for data collection was granted by the Health Research Authority and Health and Care Research Wales 21/HRA/1346-2296700.

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PEER REVIEW

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