Original Research

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Developing, Piloting and Evaluating a Therapeutic Programme for Neonates Using the Plan-Do-Study-Act Framework

Citation: Cerrito, A., Schick, K., Sutter, L., & Schmitt, K.-U. (2026). Developing, piloting and evaluating a therapeutic programme for neonates using the Plan-Do-Study-Act framework. *Interdisciplinary Journal of Nursing and Health*, 5(3), 245–258. https://doi.org/10.82051/axscgv44

Disciplines: Neonatology, Quality Improvement, Physiotherapy, Complementary Therapies

Received: April 16, 2026

Revised: September 4, 2026

Just accepted: September 23, 2026

Published: September 23, 2026

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Data Availability Statement: The anonymised data supporting the findings of this study are available from the corresponding author upon reasonable request. Public sharing is restricted due to privacy, consent, and data-protection considerations related to neonatal clinical data and qualitative interview data.

Conflict of Interest: The author(s) declare(s) no conflict of interest.

Funding: This research received no external funding.

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Abstract

Introduction. Complicated births are often associated with functional disorders in neonates. Some literature suggests alternative therapies (e.g. Craniosacral Therapy (CST) and parental education) as an appropriate substitute for stronger interventions in such cases. This pilot study aimed to develop, implement and evaluate a therapeutic programme for neonates with functional disorders based on CST and parental education in a university hospital setting.
Methods. The Plan-Do-Study-Act framework was used. The programme, named 'Wellcome', was developed using an interprofessional approach. Pain, agitation symptoms and breastfeeding problems were the functional disorders targeted. A pilot phase was implemented to investigate: i) programme usage, ii) experience of it and attitudes towards it, iii) its operationalisation, and iv) its clinical effects. Quantitative and qualitative data were collected. A stakeholder dialogue completed the evaluation phase, and a roadmap was developed for future implementation steps.
Results. The pilot phase included 25 neonates, selected mostly for breastfeeding problems (72%). The attitudes towards Wellcome were generally positive. However, several aspects of its operationalisation (e.g. inclusion criteria) should be revised based on a combination of literature research, interprofessional exchange, and possibly primary research.

The pilot study showed that the clinical effects were generally positive, although vaguely described.
Discussion. The goal described in the roadmap was to proceed with piloting and collect further data. In parallel, conflicting points regarding inclusion criteria, human resources, and scientific evidence must be addressed in a structured manner. The structure envisages an iterative process that allows rapid progression without losing the momentum gained during this first pilot phase.

Keywords: Newborn, Complicated Birth, Functional Disorders, Complementary Therapies, Quality Improvement, Pilot Study

Introduction

Despite a lack of consensus regarding a single, unifying definition, 'complicated births' are often defined as those requiring the use of instruments (forceps or vacuum) or unplanned caesarean sections (Andersson et al., 2016; Jardine et al., 2020). It has been shown that complicated births place high physiological and biomechanical stress on the neonates, with, for example, up to 200 N of additional force applied to their heads when using vacuum or forceps compared to non-instrumented delivery (Ashton-Miller & DeLancey, 2009). For this reason, complicated births are often associated with functional disorders, such as pain or distress symptoms with agitated behaviour (Mears et al., 2004; Schuller et al., 2012; Taylor et al., 2000), breastfeeding problems (Chien & Tai, 2007), or reduced cervical range of motion (often presenting as 'Positional Preference') (Fludder & Keil, 2018). As the detection of such functional disorders is not necessarily included in the medical examination of neonates during hospitalisation, they are rarely treated at this stage. When left untreated, these disorders may persist and have repercussions on the neonates' development (Boere-Boonekamp & Van Der Linden-Kuiper, 2001; Noto et al., 2021). Parents may also suffer anxiety or a sense of failure due to increased crying periods of their baby (Garratt et al., 2019).

There is some evidence that manual approaches, such as craniosacral therapy (CST), can help improve these functional disorders, particularly when used as an adjunct therapy (Deitermann & Jung, 2015; Hathaway et al., 2015; Herzhaft-Le Roy et al., 2017; Sacher et al., 2022; Shayani & Marães, 2023). More generally, the use of such complementary and alternative medical treatment options has been suggested as a means to avoid premature use of stronger interventions, such as pharmacological treatment, which bear higher risks of side-effects and can be more invasive (e.g. Hathaway et al., 2015; Shayani & Marães, 2023). However, these studies often present mixed results or methodological limitations, such as small sample sizes, highlighting the need for more research in this field. Thus, the aim of this pilot study was to develop, implement and evaluate a new therapeutic programme based on CST that focuses on neonates from complicated births and with birth-related functional disorders. The novelty of the programme lied in the combination of CST and parental education. Moreover, the novelty of this work lied in the possibility to introduce alternative treatment approaches into a university hospital setting to further support the application of the biopsychosocial healthcare model, or even the biopsychosocial-spiritual model, as advocated by some authors (Saad et al., 2017). The results of this study served as a basis for informed decision-making regarding further implementation steps and the creation of a project roadmap for a larger implementation study.

This manuscript follows the SQUIRE 2.0 framework to present the pilot study (Ogrinc et al., 2016).

Methods

Context

In Switzerland, university hospitals are the ideal environment for assessing such a therapeutic programme, given they are primary healthcare providers and therefore see high numbers of complicated births, and given their proximity

to universities, which provide the necessary scientific expertise. The University Hospital of Bern has strong connections to both Bern University of Applied Sciences and University of Bern, making it an ideal clinical environment to conduct this study. An interesting aspect of this study was the readiness of the institution to investigate non-traditional treatment approaches.

Genesis and specific objectives of the project

The project of implementing a new therapeutic programme grew organically. The idea was developed by physiotherapists at the Department of Obstetrics and Gynaecology, who began to discuss it informally with other healthcare professionals to gauge interest. The idea was well received and they contacted the Academic-Practice-Partnership research unit unit at Bern University of Applied Sciences, which specialises in conducting collaborative scientific projects with University Hospital of Bern.

The specific objectives of the project were formalised by the research team as:

1. Developing a therapeutic programme delivered by physiotherapists to neonates from complicated births and with functional disorders, as an adjunct therapy, to improve their symptoms.
2. Implementing the programme as a pilot phase.
3. Evaluating the pilot phase to obtain a fundamental dataset.
4. Discussing and deciding on further steps of implementation based on the dataset and creating a project roadmap.

To achieve these objectives, the 'Plan-Do-Study-Act' (PDSA) framework (Berwick, 1998) was used (Figure 1). Given the different healthcare professions involved in this context – including midwifery, nursing, lactation consultation, physiotherapy, and medicine (neonatology, obstetrics, gynaecology) – an interprofessional, participative approach was used (e.g. Mairhofer, 2015). In this process, the initiating group of physiotherapists (n=3) formed the development team. The other healthcare professionals formed an active advisory board to guide the development, and their consent had ultimately to be gained to participate in the programme's workflow once implemented. The entire process was orchestrated by the research team of the Bern University of Applied Sciences and is detailed in the section "Development process of the therapeutic programme".

The PDSA framework describes an iterative process frequently used in quality improvement projects. Its circular nature means it does not have the achievement of a state of 'optimal quality' as its goal, but aims to continuously improve quality. The PDSA framework was

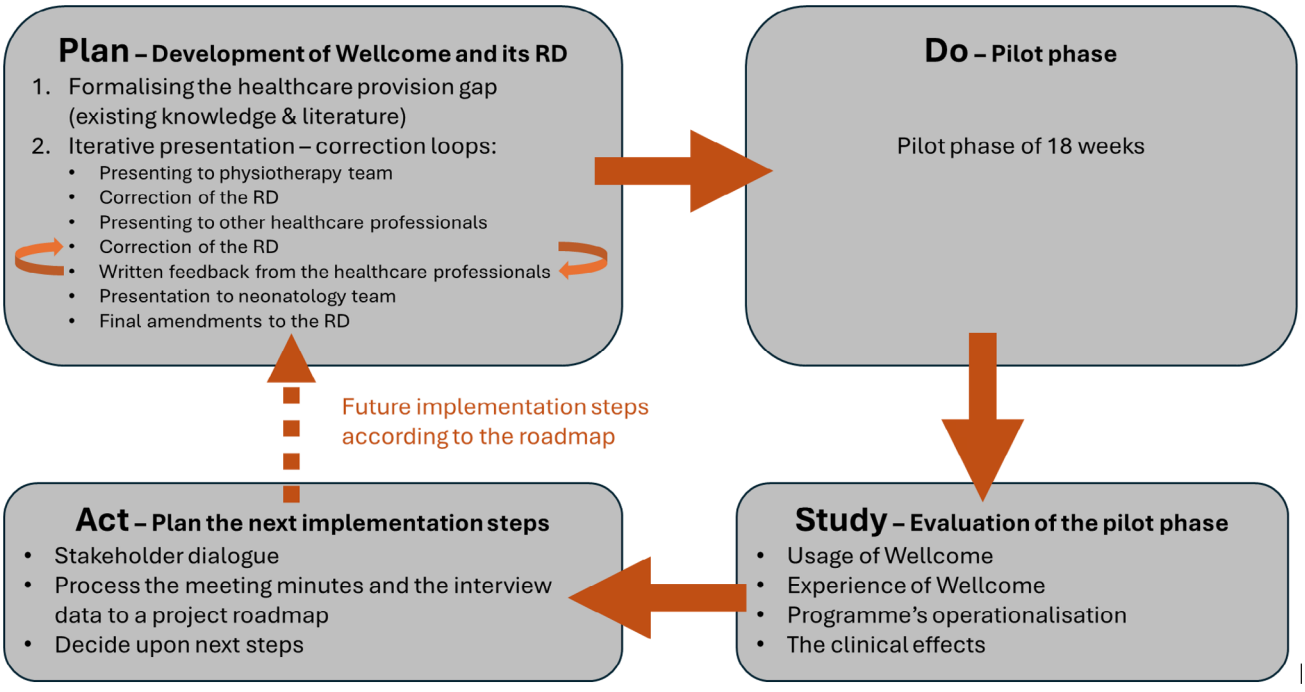


Figure 1. Plan-Do-Study-Act (PDSA) cycle used in this pilot study.

therefore selected as an ideal tool to achieve the aims of this study. The 'Plan' phase represents the planning of the intervention to be implemented, the 'Do' phase represents the implementation phase, the 'Study' phase represents the evaluation of the implementation and the lessons learnt, and the 'Act' phase represents the planning of the next steps, based on informed decision-making (Langley et al., 2009). Concrete operationalisation of these phases is described in the following sections.

Intervention: The 'Plan' phase

Development process of the therapeutic programme

Stemming from the organic genesis of the project, named Wellcome, the 'Plan' phase started with a certain supportive network. Then the network was broadened to ensure sufficient support and to obtain formal authorisation to launch a pilot phase. For this purpose, an interprofessional, participative approach was followed in an iterative process, which fed into the task of refining the Wellcome programme and writing its reference document (RD). The first step was to formalise the gap in healthcare provision. The physiotherapists were asked by the research team to list the types of functional disorder they perceived as necessary to target and to provide a working definition of 'complicated birth'. The results were compared to the available scientific literature to identify overlapping perspectives and to generate a first literature-based list of inclusion criteria for Wellcome. The same procedure was followed for the therapeutic intervention that was intended to be delivered by the physiotherapists themselves. Based on these data, the first version of the RD was drafted.

In the next step, the RD was repeatedly presented to a panel of healthcare professionals not engaged in the project and updated based on critical feedback obtained during these presentations. The first presentation was performed with the entire physiotherapy team and the supervisor to reach acceptance, if not consensus, within the team and the authorisation to proceed with the project. The second presentation was performed with nurses (n=2), midwives (n=2) and lactation consultants (n=2). This was an important step because these healthcare professionals would be involved in Wellcome. To prepare this presentation, a stakeholder analysis within these professions was performed to determine key invitees. Final decision on recruitment was based on their clinical experience and strategic roles as supervisor in their respective teams. Besides obtaining general feedback, the main focus was to gather their opinions on the proposed inclusion criteria (including the definition of a 'complicated birth' and the list of targeted functional disorders) and on the choice of standardised clinical assessment tools to evaluate the functional disorders. After updating the RD based on their feedback, intermediate steps were taken in which the RD was iteratively sent to them for review and revised until consensus was reached. The third presentation was performed with the neonatology team during one of their weekly meetings to reach as many neonatologists as possible. The neonatologists' feedback was used to finalise the RD. The authorisation of both neonatology's and gynaecology's head physicians was obtained to launch a pilot phase according to the updated RD.

The implemented version of the Wellcome programme

Wellcome targeted neonates from complicated births, defined as those requiring secondary caesarean section due to malposition of the foetal head or obstructed labour, or forceps or vacuum extraction deliveries. Among those births, neonates with agitation and/or pain symptoms as well as neonates with breastfeeding problems that could not be resolved by lactation consultants were included. Only neonates from the well-baby nursery born at term were considered for the programme. They were required to breathe spontaneously.

For the agitation and pain symptoms, the evaluation of the inclusion criteria was performed by nurses and midwives using the Bernese Pain Scale for Neonates (BPSN, score range: 0-17). Within a period of 12 hours after birth, neonates were assessed every four hours using the BPSN with a cut-off value of ≥4. According to Schenk et al. (2020), a score of ≥4 indicates pain in neonates. Breastfeeding problems were evaluated by the lactation consultants, but no consensus could be reached on a standardised assessment tool. The evaluation was based on clinical experience, mainly assessing latch quality, pain symptoms in mothers (i.e. nipple soreness), and nipple shape. Neonates that met the inclusion criteria were discussed during the neonatologist's rounds. Referral was performed by the neonatologist. The

workflows are shown in Figure 2.

The treatment included an assessment and individualised therapy. The assessment comprised an anamnesis from the parents and a physical examination of the neonates, focussing on muscle tone anomalies, asymmetries and articular ranges of motions. Therapy included CST and/or parental education, including exercises and handling instructions to foster symmetry and reduce agitation symptoms. Retest of the symptoms by the other healthcare professionals was planned 24 and 48 hours after birth.

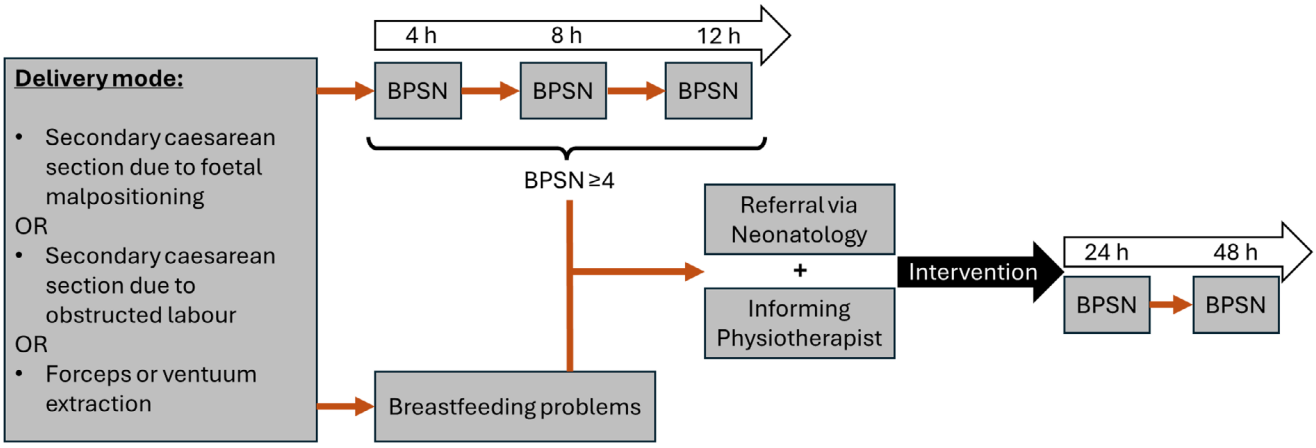


Figure 2. Illustration of the workflow defined in the RD. BPSN: Bernese Pain Scale for Neonates.

Implementation: The 'Do' phase

The pilot phase was planned for a period of four months. All nurses, midwives, lactation consultants and physicians from the postpartum ward were informed in advance about the pilot phase via email. Educational sessions, consisting of a series of 45-minute workshops, were organised to instruct them regarding their role in identifying neonates who met the inclusion criteria and how to initiate referral to the Wellcome programme. The reason why a whole series was required is that with the shifts, not all employees were present at the same time. Hence, the workshop needed to be repeated several times. During the pilot phase, no changes were made to the RD.

Study of the intervention, measures, and analysis: The 'Study' phase

General approach

Four aspects of the pilot phase were investigated: i) quantifying the usage of Wellcome, ii) exploring parents' and employees' experiences of and attitudes towards Wellcome, iii) evaluating the current operationalisation of Wellcome (i.e. how it was implemented, how the implementation was experienced, and how the workflows defined in the RD were perceived and followed), and iv) assessing the therapeutic effect, given the currently controversial state of evidence (Ceballos-Laita et al., 2024; Jäkel & von Hauenschild, 2012). In addition, although no adverse events are known from the literature on CST (Ceballos-Laita et al., 2024), the occurrence of adverse events was monitored to ensure safety of healthcare provision. Both therapeutic effects and adverse events are jointly termed 'clinical effects' hereafter.

Data collection, processing and analysis

Both qualitative and quantitative data were collected anonymously. Qualitative data were collected through semi-structured interviews performed during the last two weeks of the pilot phase with parents of treated neonates and with involved healthcare professionals (i.e. 'employees'). The interview guideline was drafted by the first author and sent to the other research team members for internal validation. The interviews with parents focussed on their experience of and attitude towards Wellcome. The interviews with employees had three foci: i) experience of and attitude towards Wellcome, ii) the level of satisfaction with its operationalisation, and iii) its perceived clinical

effects. All participants were also asked what they would suggest improving. Employee participants were recruited via advertisement posted on internal communication channels or addressed personally. All parents within the recruitment period were visited and asked whether they were interested in participating in the study. Given the early stage and the exploratory nature of the project, no specific sample size nor data saturation was targeted. The interviews were performed in person or over the phone. In-person interviews were audio-recorded using a voice recorder (Zoom H1essential, Tokyo, Japan) and phone-based interviews via MS Teams. All interviews were processed using the Rapid Identification of Themes from Audio Recordings method (Neal et al., 2015). Coding was performed by two members of the research team (LS and AC) independently. Individual results were compared and discussed to reach consensus. Themes were generated deductively and inductively for each interview focus and summarised in a MS Excel (v. 2308) document. The number of statements per theme with their valence (i.e. positive, neutral or negative statement) were summed (Neal et al., 2015). In addition, the evaluators' respective interpretations of the statements as well as their perceived importance and the statements' contexts was discussed to allow appropriate appreciation.

Quantitative data were retrieved from the clinical information system in an anonymised format after the pilot phase. These data consisted of the number of neonates included in the Wellcome programme, their respective clinical indications, the number of days between birth and first treatment, the number of treatments delivered per neonate, the number of times the workflows deviated from those defined in the RD, the changes in scores from the standardised clinical assessment tools used to evaluate the functional disorders, and the number of adverse events. The data were extracted into MS Excel, where they were synthesised using descriptive statistics (frequencies: absolute and percentage; distributions: median, minimum and maximum).

The four aspects of the pilot phase were evaluated as follows.

1. Usage of Wellcome was evaluated based on the number of neonates included with their respective clinical indications, as well as the number of treatments delivered per neonate.
2. The experiences of and attitudes towards Wellcome were explored using the interview data.
3. The programme's operationalisation was evaluated quantitatively using the time to treatment and the frequencies with which the identification of eligible neonates, the objectivation of their functional disorders and their referral to the programme complied with the RD, as well as qualitatively using the interview data.
4. The clinical effects were assessed using the changes in scores from the standardised clinical assessment tools as well as from the employees' perceptions obtained from the interviews. In addition, the number of adverse events was counted.

Planning of the next steps: The 'Act' phase

To discuss further implementation steps, a stakeholder dialogue was performed, to which the previously recruited stakeholders from nursing, midwifery, lactation counselling, neonatology, as well as members of the research team (KS and LS) were invited. The stakeholders' positions regarding the implemented version of Wellcome as well as future implementation steps were discussed in light of the results from the 'Study' phase. Discussion minutes were taken. A fair copy was written and sent to all stakeholders for validation. They were allowed to amend the copy if required.

The stakeholder dialogue, together with the interview data, formed the basis of a project roadmap. The text passages from the meeting minutes were first grouped thematically into categories and subcategories. A summary outlining the main consensual and conflicting points was composed for each subcategory. The conflicting points and unresolved questions were listed together with a corresponding list of tasks to tackle them. Finally, links between these points requiring action to be resolved were identified, allowing a brief network analysis using MS Excel. In this analysis, a link represented the case where a task structurally depended on another. Subcategories were ranked according to their number of links to other subcategories, i.e. degree centrality (Rodrigues, 2019), to prioritise tasks in the roadmap.

Ethical considerations

No ethical approval was required for this project since it did not fall under the Swiss Federal Human Research Act (Req-2024-00513). Nonetheless, the Declaration of Helsinki was respected. Informed consent to collect data was obtained from all included neonates' parents once they had started the programme.

Results

Results from the Study phase

All required quantitative data could be retrieved from the clinical information system. For the interviews, there was a total of 13 participants. Five interviews were conducted with parents. From the employees (7 female, 1 male), two were neonatologists, two physiotherapists, two midwives, one nurse and one lactation consultant. Overall, they had a median working experience of 12.2 years (range: 1.5–35).

Usage of Wellcome

The pilot phase lasted 18 weeks (~4.5 months). In this period, 25 neonates were included in Wellcome. Most cases were included due to breastfeeding problems (n=18, 72%), followed by agitation and/or pain symptoms (n=2, 8%) and a combination of both (n=3, 12%). Other symptoms, such as foot deformities and parental worries, were included in two cases (8%). A median of one treatment was delivered per case. One treatment was delivered in 20 cases, and a maximum of two treatments was delivered in five cases.

Experience of and attitudes towards Wellcome

Parent interview data were categorised into three themes: 'Physical symptoms', 'Psychological symptoms, stress, and mental wellbeing', and 'Embeddedness in hospital stay' (Table 1). No negative statements were provided for any theme. In total, 19 positive and five neutral statements were provided for this interview focus. The favourable attitude towards Wellcome was due to 42% (n=8 statements) to experiencing improvements in physical symptoms, mainly feeding- and digestive or urinary system-related symptoms, and stiffness symptoms that hindered physiological head movements. In addition, 32% (n=6 statements) of the answers reflected a positive effect on parental psychological state and stress levels, as well as improved calmness of neonates. Interestingly, some interviewees described their experience as positive but were unable to define the reasons. Finally, 26% of the positive statements concerned the embeddedness of the programme in the parents' hospital stay, including the fact that Wellcome is a low-threshold service, and that the symptom improvements led to a reduced use of the nurse call bell. Neutral statements consisted of one case that found it difficult to evaluate the benefit and other encouraging words supporting the permanent implementation of the programme.

Employee interviews were categorised into two themes: 'Meaningfulness', with 12 positive and one negative statement; and 'Values', with 10 positive and one neutral statement. It was mentioned by all interviewees that Wellcome was meaningful, even though this view was sometimes based on knowledge of what the programme intended to achieve rather than on personal experience of its benefits. Wellcome was described as a meaningful adjunct to cover an important gap in healthcare provision, particularly because it facilitated identification and treatment of functional disorders early in a neonate's life. Moreover, it was seen as a great support to alleviate parental stress. The notion of 'providing an optimal start in life' was also perceived as an important value the programme represents. Also, provided it is not harmful, the programme was valued as one more service that increases the chances to promote neonates' health, hence it is worth adding. This was particularly influenced by its perception as a low-threshold service. However, one interviewee critically questioned its meaningfulness in relation to best use of human resources when the programme is based on limited scientific evidence and this is a time of skills shortage. One neutral statement noted the need to obtain parental consent before beginning treatment, irrespective of any perceived value of the programme.

Evaluation of the operationalisation

The median time between birth and first

treatment was two days. In three cases, the treatment was initiated the same day, in nine cases after one day, in eight cases after two days, in four cases after three days, and in one case after four days. Out of the five neonates included for agitation and/or pain symptoms (n= 2 plus n=3 in combination with breastfeeding problems), only one was evaluated using the BPSN. The other case did not include objectivation of the symptoms and the reasons could not be elucidated. Given that no consensus could be reached on an assessment tool for breastfeeding problems, no compliance analysis could be performed for these cases. Referral was performed according to the workflows described in the RD 32% of the time (n=8). Most cases (n=17, 68%) were not referred according to the set workflows, with most deviations (n=15, 60%) being the inclusion of neonates that did not meet the birth criteria. The remaining 8% comprised a neonate that experienced a forceps delivery but did not meet the set scope of functional disorders and one that met no criteria at all.

The interview data contained 10 positive, seven neutral and 27 negative statements on how the implemented version of Wellcome was experienced (Table 1). The positive statements mostly comprised feedback on the workflows themselves (50%), which were most frequently considered to be straightforward, and on the interprofessional collaboration (40%). The same themes contained the most negative statements. Statements concerning the interprofessional collaboration (33%) most frequently contained feedback on heterogeneous levels of acceptance regarding Wellcome among colleagues and insufficient introduction to the programme. The negative statements on 'Workflow' (30%) mostly referred to the additional effort imposed by Wellcome (e.g. performing the BPSN repeatedly or having to remember to identify eligible neonates and refer them to the programme in an already hectic clinical routine). Another substantial theme on the negative feedback side consisted of the inclusion criteria (19%), which covered contradictory statements. On the one hand, a group of interviewees felt that the inclusion criteria were too restrictive. Inclusion of neonates based strictly on pain/agitation symptoms and breastfeeding problems was thought to result in excluding many cases with other symptoms that could have benefited from Wellcome. Similar feedback was provided regarding the BPSN cut-off value of ≥4, which was thought to be too high. It was also proposed that inclusion should rely less on criteria and more on evaluation based on clinical experience. On the other hand, the lack of clear inclusion criteria for breastfeeding problems was also criticised and the only positive feedback in that theme was that the BPSN provided clarity due to its objective nature. A final theme labelled 'Others' mostly covered statements deploring a difficult starting phase due to insufficient information and presence of the programme

Table 1. Interview foci and themes identified using the Rapid Identification of Themes from Audio Recordings method from parent and employee interviews. The number of positive, neutral and negative statements are presented.

	Interview focus	Theme	Statements		
			Positive	Neutral	Negative
PARENTS	**Experience & Attitudes**		**N=19**	**N=5**	**N=0**
		Physical symptoms	n=8	n=2	n=0
		Psychological symptoms	n=6	n=0	n=0
		Embeddedness	n=5	n=3	n=0
EMPLOYEES	**Experience & Attitudes**		**N=22**	**N=1**	**N=1**
		Meaningfulness	n=12	n=0	n=1
		Values	n=10	n=1	n=0
	Operationalisation		**N=10**	**N=7**	**N=27**
		Workflows	n=5	n=0	n=8
		Interprofessional collaboration	n=4	n=4	n=9
		Inclusion criteria	n=1	n=1	n=5
		Others	n=0	n=2	n=5
	Clinical effect		**N=12**	**N=3**	**N=2**
		Agitation	n=4	n=0	n=1
		Breastfeeding	n=3	n=0	n=1
		Mother-child dyad	n=2	n=0	n=0
		Others	n=3	n=3	n=0

initiators, as well as the implementation being timed in parallel with the launch of a new clinical information system. The statements regarding the later stage of the pilot phase confirmed that these aspects had improved. The seven neutral statements concerned the same aspects as the positive and negative statements under the 'Interprofessional Collaboration' (57%), 'Inclusion Criteria' (14%), and 'Others' (29%) themes, but were simple descriptions of their experiences, without judgement.

Clinical effect

The BPSN was performed once to include a neonate and evolved from a score ranging from 4 to 5 up to 20 hours postpartum, to a score of 3 after therapy. No quantitative analysis could be performed for the therapeutic effect on breastfeeding problems since no standard assessment tool was used. No adverse event was reported.

The interview data showed 12 positive, three neutral, and two negative statements in four themes (Table 1). Most positive feedback was provided on improvements in agitation symptoms (33%). One interviewee had observed these improvements, two heard of them via parental feedback, and one reported the improvements based on both. Second most frequent positive effect was reported on breastfeeding problems (25%), which was directly observed by two interviewees out of three. The positive effect on the mother-child dyad was also mentioned (17%), particularly as a secondary effect from the decreased parental stress. The remaining statements (25%) were categorised under the theme 'Others' and grouped statements on the positive experience of parents who were involved in the therapy via the educational part of the intervention, as well as the theoretical benefit of the programme. Two neutral statements mentioned that the general effect (i.e. concerning all themes of this interview focus) was unclear. This was moderated by a third statement advancing the view that if there were no benefit, at least there was certainly no harmful effect. Two statements were more critical. One warned that some functional disorders could improve without treatment, as was observed by the interviewee directly in an eligible neonate that ended up receiving no therapy. The other reported, from direct observation, no effect in two out of five breastfeeding problems.

Results from the Act phase

The stakeholder dialogue gathered six participants, such that all invited professions were represented by at least one person. After the dialogue, the meeting minutes was amended by two persons, while one person reported having no comments and three did not respond. From the corrected meeting minutes, eight subcategories were identified, which were grouped into four categories (shown in Figure 3). The subcategories are ranked in Table 2 according to their priorities, based on degree centrality, and presented grossly with their most important conflicting points and unresolved questions that must be addressed, along with suggested approaches. Figure 3 presents a graphical representation of the resulting roadmap. It was designed as an iterative process with two 'routes'. First, the 'knowledge route', whereby a common knowledge base shall be obtained, primarily regarding inclusion criteria (including the definition of a complicated birth). This should be performed through scientific literature research and interprofessional work shadowing to synthesise best current evidence and to level the practices, respectively. Second, the 'exchange route' foresees interprofessional discussions to develop improved inclusion routines and to decide upon the amount of evidence required to justify definitive implementation from a resource and ethical perspective. These discussions shall be informed by the work done in the knowledge route. After each cycle, the RD will be updated and a new pilot phase chapter will be launched, generating further data and gaining additional experience. In parallel, other tasks (e.g. preparing information flyers, or discussing general prescription possibilities) could be performed relatively independently of the order of the two routes. It is important to note that the roadmap explicitly recommends planning many iterations, each with reasonably small goals that can realistically be achieved in a relatively short period of time. This has the advantage of a short discontinuation period of Wellcome, therefore the benefits of the first pilot phase's momentum can be utilised. The full roadmap can be found in the supplementary material.

Table 2. Subcategories identified from the meeting minutes of the stakeholder dialogue ranked according to their degree centrality in descending order.

Inclusion Criteria (Degree Centrality: 9)

It is unclear whether more or less objective criteria should be used. Objective criteria would foster evidence-based medicine. However, psychometric properties of existing assessment tools, most reliable time point to use them and the time/effort required to use them are unclear. In contrast, even in medicine many interventions are not evidence-based, such that a less criterion-based approach (i.e. need-oriented) could be considered. The question to tackle is:

What are the optimal inclusion criteria (from an evidence-based practice, ethical and resources perspective)?
Suggested approaches:

- Systematic literature review to map existing assessment tools and list respective: psychometric properties (reliability, diagnostic validity, predictive values), time/effort required to perform, and most reliable time points to use.
- Interprofessional work shadowing to compare knowledge and perspectives.

Resources (Degree Centrality: 7)

It is unclear whether the required human resources can be justified for a programme that has weak evidence. From this perspective, Wellcome could be interpreted as a wellbeing programme (i.e. need-oriented). The majority of resources would be at the expense of the physiotherapy team. Other professions did not report substantial additional time costs involved with Wellcome, except for performing the BPSN, which is time-consuming. The question to tackle is:

What are the criteria to justify the resources required for Wellcome (in terms of scientific evidence, hospital policy, and operationalisation efficiency)?
Suggested approach:

- Discuss with hospital managers/supervisors how many resources can be mobilised for a given level of scientific evidence, based on current hospital policy and on the knowledge from the previous literature review on operationalisation efficiency (i.e. time required for a given assessment tool with a certain diagnostic sensitivity and specificity).

Evidence (Degree Centrality: 7)

Insufficient therapeutic evidence was obtained from the pilot phase to draw any conclusion. But given the preliminary results appear to be relatively positive, the programme should be continued to collect further data. Then, plans for a more robust scientific investigation could be discussed. However, it is unclear how much evidence is required. The question to tackle is:

What is the 'right amount' of evidence and how can it be generated?
Suggested approach:

- Improve the programme based on the previous systematic literature review (Inclusion Criteria) and proceed with the programme to collect further data for another approximately seven months (i.e. dataset from a total duration of approximately 12 months).
- Based on the collected data, further scientific steps should be discussed with managers/supervisors regarding the required evidence and with research partners regarding research options.

Time Points (Degree Centrality: 3)

It is unclear whether assessing the targeted functional disorders as shortly after birth as was performed was beneficial. The same holds true for the intervention. It is conceivable that assessment tools are insufficiently sensitive so early in life and that neonates with seeming indications could possibly regulate themselves without intervention. However, hospital stay is very short, therefore a longer wait is not feasible. The question to tackle is:

What are the optimal time points to assess and treat the neonates?

Suggested approach: These aspects are covered in Inclusion Criteria and Evidence.

Others (Degree Centralities: 0–3)

Other aspects of less importance due to lower degree centrality values, less significance to the programme and/or requiring less preparatory work, included:

- **Effect:** investigating the natural history of the targeted functional disorders to obtain a better understanding of what to expect from the intervention.
- **Dissemination & Opposition:** distribute flyers, present current results to the teams, and directly address colleagues with negative attitudes to promote Wellcome and reduce opposition to it.
- **Referral:** investigate ways to improve referral efficiency (e.g. possibility for general prescription).

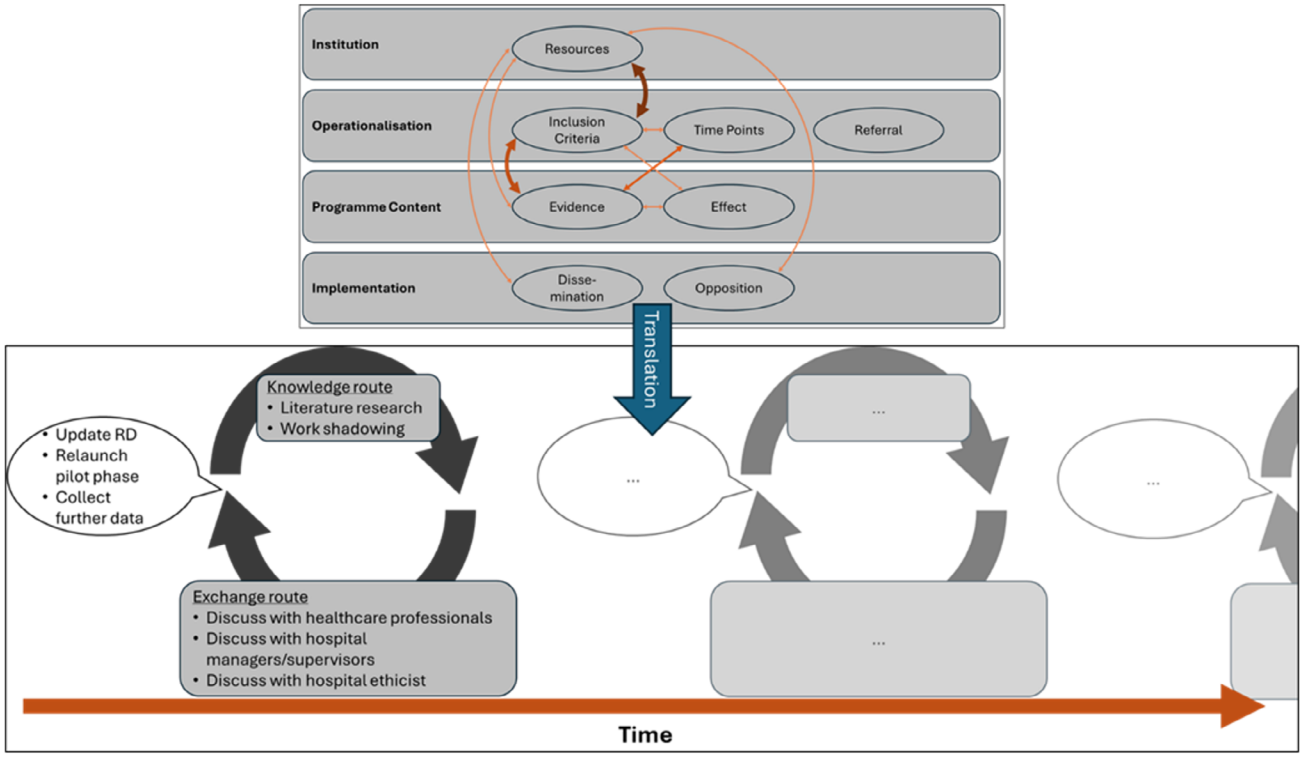


Figure 3. Top: illustration of the (sub-)categories identified from the meeting minutes of the stakeholder dialogue with their interconnectedness (orange arrows). The stronger the connections (i.e. higher degree centralities), the bolder and darker the arrows. Bottom: these topics were translated into the roadmap, which is represented as repeated cycles over time.

Discussion

In this pilot study, a therapeutic programme based on CST and parental education was developed in an interprofessional team to improve healthcare provision for neonates with functional disorders. The programme was implemented in a 18-week pilot phase, during which data were collected to evaluate programme usage, experience of and attitudes towards it, its operationalisation, and its clinical effects. The results of the evaluation showed that the programme found traction, given it included a total of 25 neonates, equating to a weekly average of 1–2 new cases, and given that most attitude- and experience-related feedback from parent and employee interviews was positive. Most positive parental views concerned perceived physical or mental benefits from the intervention, although precise descriptions were often lacking. Employees' positive attitudes mainly related to the perceived meaningfulness of Wellcome and the values it represents. Based on these results, it was suggested in the stakeholder dialogue to proceed with further piloting to collect additional data and gather more experience.

Several negative points were also raised during the pilot phase. Negative feedback from the interviews focussed mainly on how the programme was shaped and/or implemented (i.e. additional effort, suboptimal inclusion criteria, lack of acceptance by some colleagues). These results were reflected in the quantitative analysis, which showed lack of adherence to the workflow and criteria described in the RD in 68% of the cases. These topics were corroborated by the stakeholder dialogue. Taken altogether, these results allowed a prioritisation of the observed concerns. A major and multifaceted issue arose in the inclusion criteria. For example, some proposed less strict criterion-based selection, while others suggested adding further criteria, e.g. for breastfeeding problems, to improve clarity in decision-making. The issue also has implications for other aspects of the programme that were criticised, such as the utilisation of human resources. Choosing shorter pain/agitation assessment tools could, for instance, alleviate the additional effort imposed by Wellcome's workflow. More importantly, the issue of suboptimal inclusion criteria raises the question to what extent additional human resources can be mobilised if the indications remain vague. In any case, refining inclusion criteria appears to be highly important, since not respecting them represented 60% of all cases where the procedure deviated from the defined workflow.

More generally, it is unclear how much scientific evidence is required to justify the definitive implementation of Wellcome. Not only is this a question of resource utilisation, but it is also an ethical question (e.g. Vineis, 2004), asking whether neonates should be treated with CST and whether workforce should be used for this purpose if the evidence for clear indications and for efficacy is weak.

In any case, this situation also leads back to the need to collect further data and, on a more general level, to acquire a stronger knowledge base, also from the literature. For example, while two systematic reviews indicate weak efficacy results for CST (Ceballos-Laita et al., 2024; Jäkel & von Hauenschild, 2012), other studies that were not included in these reviews appear to show positive effects on breastfeeding (Herzhaft-Le Roy et al., 2017) and on length of hospital and/or newborn intensive care unit stay for preterm babies, with a reduction ranging from 3.9 to 5.9 days (Cerritelli et al., 2013, 2015; Pizzolorusso et al., 2014). It must be noted that these studies showing positive effects used osteopathic treatment (Herzhaft-Le Roy et al., 2017), rather than CST alone, and recruited preterm neonates (Cerritelli et al., 2013, 2015; Pizzolorusso et al., 2014), unlike Wellcome. Strengthening the knowledge base will not only help make the RD more evidence-based but will also clarify the need to conduct further research.

Other aspects, such as opposition to Wellcome by certain employees, the lack of presence of the physiotherapists in the daily clinical routine to promote Wellcome, and the issue of the prescription, were considered to be minor issues by the research team when compared to the more fundamental questions highlighted above. For this reason, their related list of tasks was organised in such way that it could be worked through in parallel. For example, to alleviate resistance to change, employee involvement will be further increased through regularly presenting preliminary results in the teams as iterations are completed (Freddy & Mbohwa, 2013). This employee involvement effect will be supported by the planned work shadowing and interprofessional discussions. Furthermore, additional information events and flyers should be held and distributed, respectively, and negative attitudes should be addressed individually.

Strengths and limitations

This pilot study's main strength lies in the innovative aspect of the therapeutic programme. Craniosacral therapy is rarely offered as a healthcare service at hospital and, to our knowledge, never in university hospitals in Switzerland. Hence, this is pioneering work and reveals potential for wider implementation. The methods used to develop the programme and the selected outcomes were also perceived as strengths. The participative approach used in the development phase fostered interprofessional collaboration and promoted acceptance of the programme. The diversity of outcome measures permitted a holistic evaluation of the pilot phase.

In contrast, the study's main limitation was a possible selection bias effect. Indeed, the recruitment strategy failed to include employees with negative attitudes towards Wellcome, which meant the reason for their opposition could not be determined explicitly. The same possibly applied with the recruited parents. It is conceivable that mainly parents who had pre-existing penchant for complementary and alternative medical treatment options accepted to participate.

Conclusions

In conclusion, the PDSA cycle completed in this pilot study paved the way for future implementation studies and showed that attitudes towards Wellcome were generally positive. Hence, proceeding with further piloting to collect additional data and gain more experience was recommended. Based on this result an easy-to-use project roadmap was devised, which retains the essence of the current pilot study's approach. That is, through proceeding with pilot phases, along with progressive improvement via more profound literature research, interprofessional exchanges and potential evidence generation, the programme will organically lower opposition and reach establishment within clinical routine. Moreover, the proposed methodology of iterative cycles matches the philosophy of PDSA very well, such that it can be easily embedded in that framework in future implementation studies.

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