

The 4th Trimester Initiative
A Randomized Controlled Trial of Support for Childbearing Medical Trainees

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HARVARD MEDICAL SCHOOL
TEACHING HOSPITAL

Mass General Brigham

Disclosures

No financial, industrial, or professional conflicts of interest

Changing the Culture Around Parenthood in Medicine

How we got here

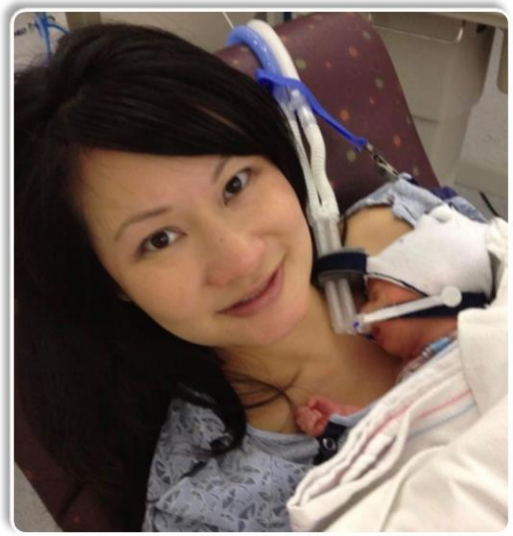
To set the stage, I want to briefly show how this work evolved.

1. Why this work matters to me
2. Why it matters for the physician workforce
3. Why culture resists change
4. What it takes to change culture
5. **How we built buy-in**
   Define the problem • Understand stakeholders • Develop solutions • Show return
6. **Today's focus: proving ROI in a pragmatic trial**

→ From there, I'll turn to the trial itself.









Challenges in Pregnancy and Training Shape Career Outlook



JAMA Surgery

Rangel et al., JAMA Surgery, 2018

Factors Associated With Residency and Career Dissatisfaction in Childbearing Surgical Residents.

Surgical Residents Say

86%	Worked unmodified schedule till birth though 73% had health concerns
60%	Felt stigma related to pregnancy
78%	Had ≤6 weeks maternity leave
85%	Uncomfortable asking to scrub out of case to pump
66%	Dissatisfied with mentorship on balancing family and career



Career Dissatisfaction

40%	strongly reconsider whether they wanted to stay in surgery
27%	preference for a career more accommodating of pregnancy and family
30%	would caution female medical student against choosing surgery

These were not simply lifestyle preferences; adverse training experiences were associated with how residents viewed the sustainability of a surgical career.

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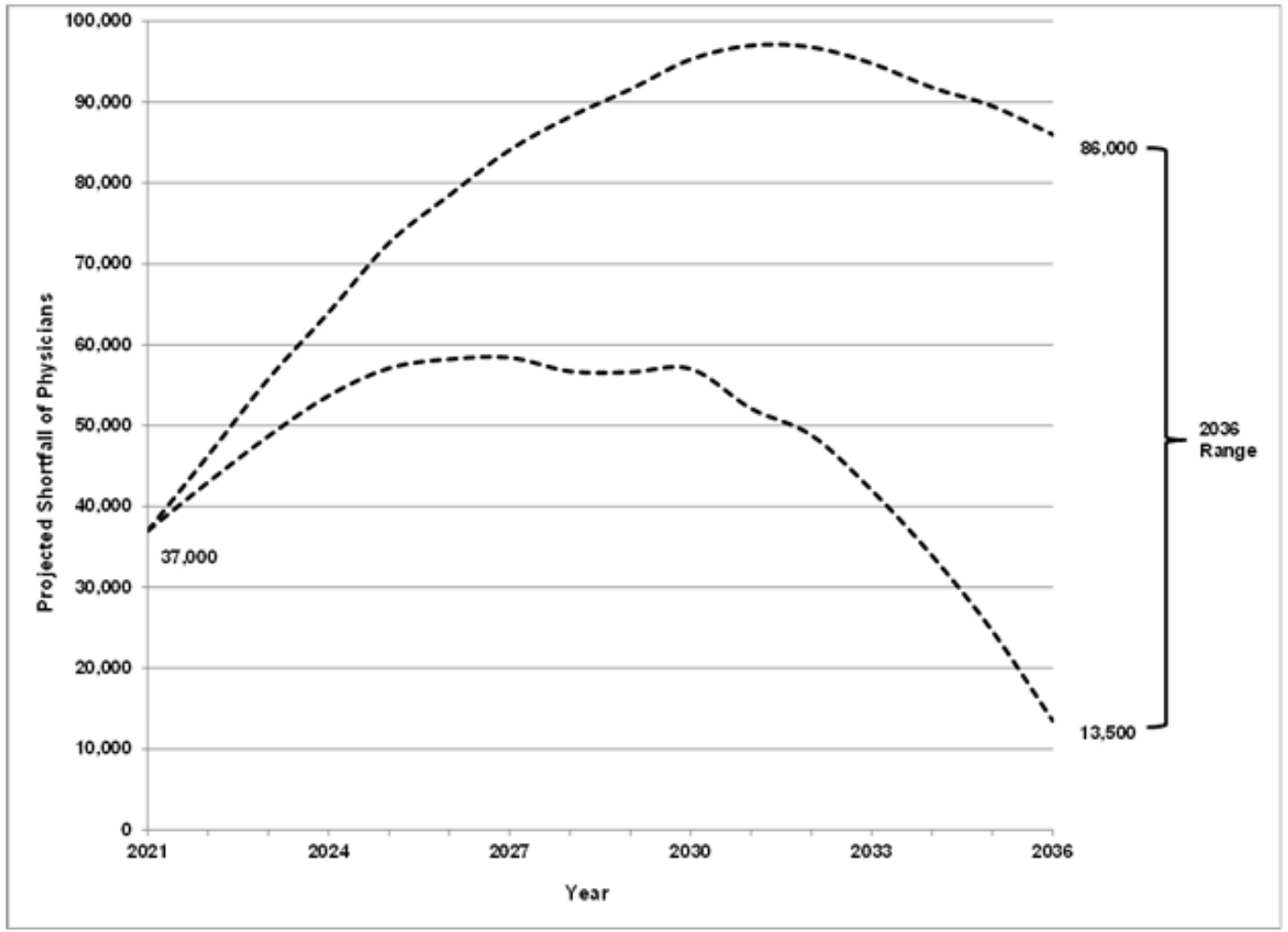
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The Complexities of Physician Supply and Demand:
Projections From 2021 to 2036

AAMC

Exhibit 2: Total Projected Physician Shortfall Range, 2021-2036





Statistics on the Shifting Surgeon Workforce

1. Predicted shortage of surgeons by 2036: 10,000–19,900 surgeons
2. Number of US states that currently have fewer than 7.5 general surgeons per 100,000 population: 21
3. Portion of surgeons in the US who are age 65 years or older: Approximately 25.6%
4. Estimated number of surgeons older than age 65 who may retire without a replacement: 10,937



PEW RESEARCH CENTER | MAY 27, 2020

As Millennials Near 40, They're Approaching Family Life Differently Than Previous Generations

- 71% young physicians cite family time as an important factor in a desirable practice
- Dual career couples are increasing
- Dads see parenting as central to their identity
- Work-home conflict breeds burnout

Heroic Martyrdom

“Back in my day, I walked to school 5 miles uphill in the snow ….”



JAMA Surgery | Original Investigation

Pregnancy and Parenthood Among US Surgical Residents

Ruojia Debbie Li, MD, MS; Lauren M. Janczewski, MD, MS; Joshua S. Eng, PhD; Darci C. Foote, MD, MS; Christine Wu, MD; Julie K. Johnson, PhD; Sarah Rae Easter, MD; Eugene Kim, MD; Jo Buyske, MD; Patricia L. Turner, MD; Thomas J. Nasca, MD; Karl Y. Bilimoria, MD, MS; Yue-Yung Hu, MD, MPH; Erika L. Rangel, MD, MS

The SECOND Trial

2021 ABSITE Survey



Ruojia Debbie Li, MD, MS



Lauren M. Janczewski, MD, MS

82%
response rate

6876
total general surgery residents

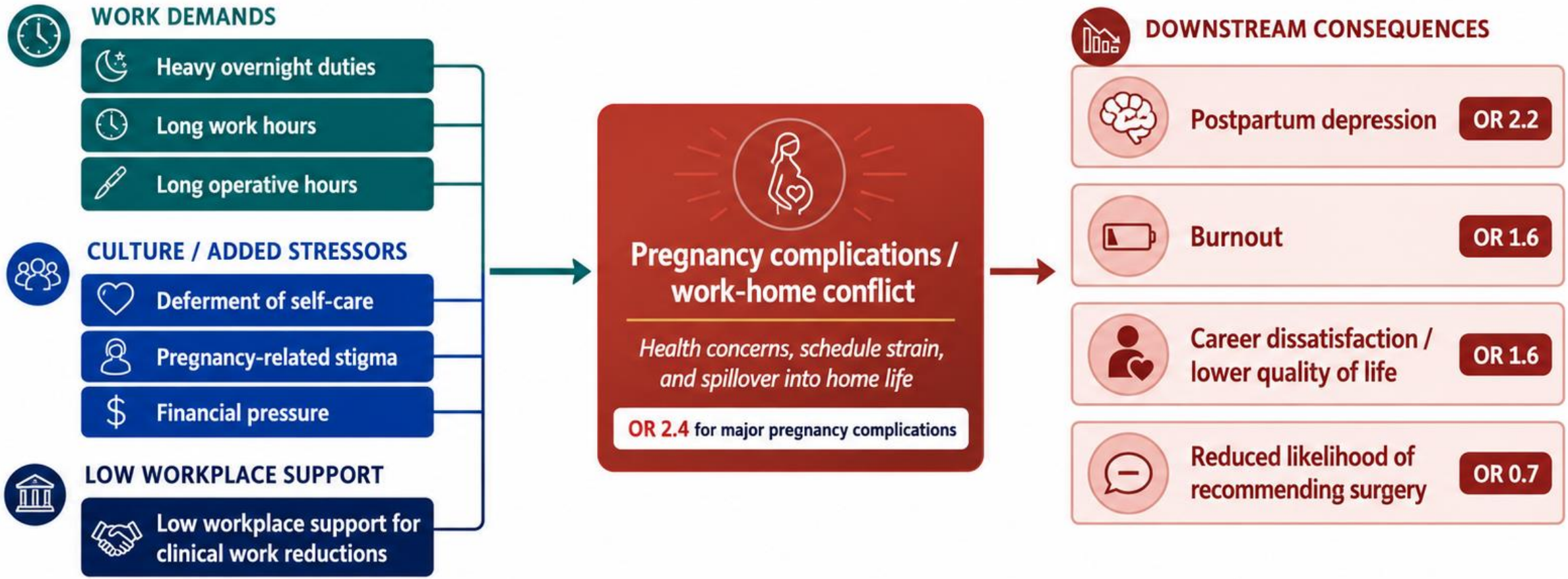
10%
of female residents have children during clinical training

58%
mistreated

- Gender discrimination
- Discrimination due to pregnancy/childcare
- Bullying

This Was Not Merely Dissatisfaction

Across our prior work, the pattern was consistent: working conditions and workplace culture translated into health and career consequences.



Key message: This was not just dissatisfaction; it was a pathway from working conditions to health, well-being, and career consequences.

Occupational well-being is often misunderstood

Not a wellness perk problem. An implementation and evidence problem.

WHAT IT IS **NOT**



- Mindfulness retreats
- Yoga on the lawn

WHAT IT **IS**

- Clinician engagement
- Career satisfaction
- Professional longevity
- Reduced turnover
- Increased quality of care

To tackle occupational well-being, we had to address two barriers at once:

1 Overcome resistance to change

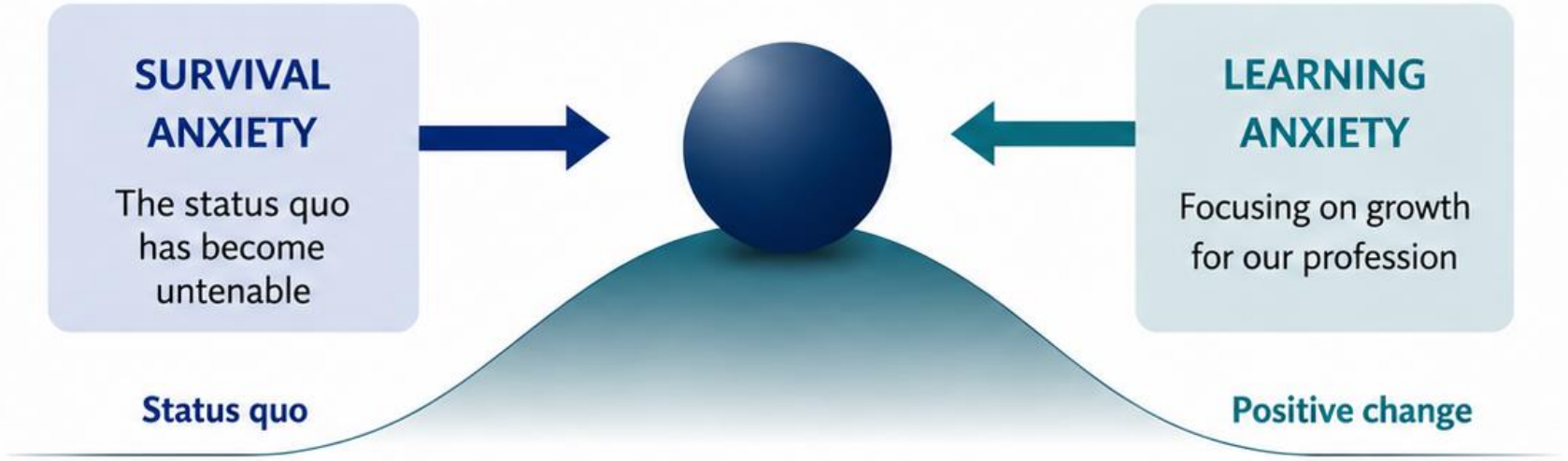
Design interventions that are feasible, acceptable, and within the locus of control.

2 Prove return on investment

Generate well-designed evidence that organizations can act on.

Changing the Culture Around Parenthood in Medicine

A Culture Shift: From Surviving to Thriving



Survival Anxiety:

- Burnout
- Poor surgeon and fetal health
- Dissatisfaction
- Deterring medical students

Tackle Learning Anxiety:

- We are not trying to reduce training.
- We are not erasing what makes us great.
- What will the costs be?
- Will it make a difference?

ROI =

- Reduced burnout
- Recruitment/Retention
- Longer career longevity
- Better productivity
- Improved maternal-fetal health



- Money
- Resources
- Policy
- Staffing changes



The 4th Trimester Initiative: Study overview



Why burnout became the anchor outcome

A personal harm becomes an institutional signal when it predicts workforce loss, clinical effort, and quality.

Human consequences

- Relationship strain
- Alcohol/substance use
- Suicidality

$4.6B/year

Estimated annual cost of physician burnout to the U.S. healthcare system

$7,600 per physician

Organizational consequences

- Attrition
- Reduced clinical effort
- Medical errors
- Lower quality of care

For leaders, burnout translates individual suffering into a measurable workforce and ROI outcome.

Han et al., Ann Intern Med, 2019

Roadmap for Today's Discussion

1



The problem was real, but not everything was solvable

Stigma, sleep disruption, lactation barriers, work-home conflict, mentorship gaps, and low workplace support.

2



Pragmatic design starts with locus of control

We targeted supports that were evidence informed, portable, accessible, and financially plausible.

3



Build a package that could actually be delivered

Bassinet, wearable pump, virtual perinatal care, and faculty mentorship.

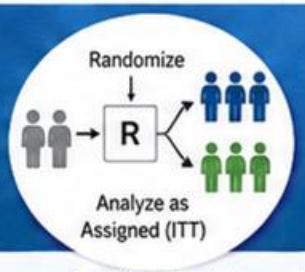
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Preserve the messiness of the real world

Controls could buy components, leave plans could change, and participants could choose what to use.

5



Make analysis choices that preserve the question

Intention to treat for assigment; planned leave in primary models; actual leave and utilization as exploratory.

6



Did it work, and could it work in practice?

Primary burnout results, supportive secondary findings, utilization, cost, scalability, and next steps.

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We began by mapping the full problem space

Childbearing trainees face multiple overlapping challenges across work, home, and the interface between them.

- **Childcare**
  Availability, affordability, and reliability
- **Parental leave**
  Duration, flexibility, and policy clarity
- **Lactation support**
  Time, space, equipment, and workflow
- **Schedule flexibility / coverage**
  Workload redistribution and clinical coverage
- **Culture and stigma**
  Guilt, stigma, and perceived burden on peers
- **Work-home conflict**
  Competing clinical and family demands
- **Maternal health**
  Prenatal, postpartum, and recovery needs
- **Sleep / fatigue**
  Work demands, infant care, and disrupted sleep
- **Access to care**
  Prenatal, postpartum, mental health, and pediatric care
- **Mentorship / workplace support**
  Advocacy, navigation, and role modeling

This mapping exercise helped us ask:

1. Which challenges mapped onto recognized burnout domains?
2. Which could ultimately be addressed through reproducible supports?

Key message: We first mapped the known challenges surrounding pregnancy, leave, and return to work before narrowing to trial-ready supports.

Those challenges converged within recognized burnout domains

Different stressors clustered within a common set of work-system domains that shape burnout in childbearing trainees.



Key message: Burnout was a compelling primary outcome because many distinct challenges converged on the same underlying domains.

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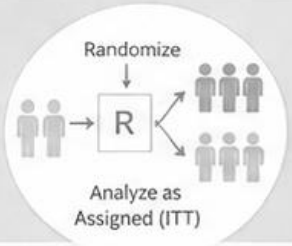
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Pragmatic Design Starts with Locus of Control

Many important challenges emerged, but we had to focus on supports we could directly deliver to trainees—without relying on local culture, personalities, or system-level change.

Broader support needs that mattered

- **Childcare**
  Expensive, location dependent, and highly variable by family.
- **Parental leave duration**
  Critical, but largely determined by program policies and local culture.
- **Lactation space and support**
- **Schedule flexibility / coverage**
- **Culture and stigma**
- **Work-home conflict**
- **Maternal health**
- **Sleep / fatigue**
- **Access to care**
- **Mentorship / workplace support**

Each candidate intervention had to meet several criteria

- Evidence of benefit
- Relevant to an identified stressor or need
- Could be delivered directly to the trainee
- Reasonable implementation burden and cost
- Not dependent on local infrastructure, culture, or gatekeepers
- Financially plausible

What this meant for trial design

We accepted that some important needs would remain outside the intervention.

We prioritized supports the study team could deliver consistently across institutions.

The intervention was deliberately **pragmatic**, not comprehensive.



Key message: We focused our trial on high-impact supports we could deliver directly to trainees—without relying on local culture, personalities, or system-level change.

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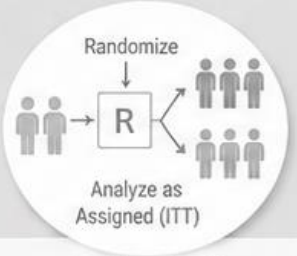
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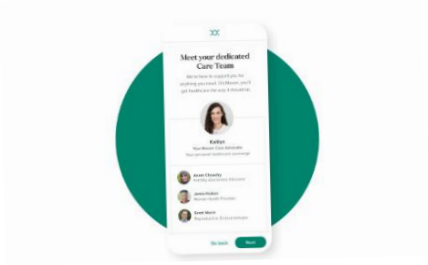
The 4th Trimester INITIATIVE



Wearable breast pump



Smart bassinet



24/7 perinatal care app



Faculty mentorship

Faculty Mentorship Was Evidence-Informed

Qualitative work documented the need, and prior scholarship plus a physician parent well-being network suggested that this support was feasible to deliver.

A DOCUMENTED NEED

I needed more mentorship regarding resources available and how not to compromise training. But the problem is ***very few female attendings were mothers*** *at my program."*

PRIOR WORK



Perspectives of pregnancy and motherhood among general surgery residents: A qualitative analysis

Erika L. Rangel [a,c,*], Manuel Castillo-Angeles [a,c], Marguerite Changala [a,c], Adil H. Haider [a,c], Gerard M. Doherty [b], Douglas S. Smink [b,c]



A Pregnant Pause—Time to Address Mentorship for Expectant Residents

Alessandra L. Moore, MD[1]; Douglas S. Smink, MD, MPH[2,3]; Erika L. Rangel, MD, MS[2,3]

> Author Affiliations | > Article Information

JAMA Surg. 2022;157(10):867-869. doi:10.1001/jamasurg.2022.1835



FEASIBILITY AND LIVED-EXPERIENCE SUPPORT

Mass General Brigham | Physician Parent Well-Being Network





Mentorship addressed a documented need for guidance, advocacy, and navigation during pregnancy and early parenthood in training.

Mentorship fit the package because it addressed social support, values alignment, and work-family navigation while remaining low-burden and directly deliverable to trainees.

Wearable Pump Addressed a Practical Lactation Barrier

Qualitative work documented unmet lactation needs, and prior studies highlighted how often pumping was disrupted during surgical training.

A DOCUMENTED NEED

AJS The American Journal of Surgery®

Nearly 50% of physicians do not meet their breastfeeding goals

> *II definitely needed more places to pump more conveniently. Having computers in pump rooms. Dedicated pump rooms in the OR. Even ones that I could share with other women with a fridge would have been hugely helpful!*
>
> *Rangel et al. Am J Surg 2018*






PRIOR WORK

Breastfeeding Medicine®

Original Research | 2024

One Pump at a Time: A Wearable Lactation Pump Pilot for Graduate Medical Education Trainees

Sheffield V, Tomlinson S, McCaffery H, McCormick AD

- Pilot distribution of wearable pumps to trainees
- Decreased perceived impact of lactation on clinical care, medical education, and missed pumping sessions
- All pump users reported the pumps helped meet lactation goals.

WHY WE CHOSE THE WEARABLE PUMP



- Targeted lactation logistics during clinical work
- Directly deliverable to the trainee
- Low implementation burden for the program
- Addressed one pragmatic part of a broader lactation problem

The wearable pump fit the package because it addressed a concrete, documented barrier while remaining low-burden and directly deliverable to trainees.

Smart Bassinet Offered a Pragmatic Sleep Countermeasure

Postpartum sleep disruption was one of the few early-parenthood stressors we could address directly. Although the device cost about $1,600, small studies suggested benefits for infant sleep, caregiver sleep, caretaking stress, and mood.

A COSTLY BUT TANGIBLE SUPPORT

$1,600

enough to make many trainees hesitate to buy it on a resident or fellow salary.

Targeted nocturnal wakefulness and postpartum sleep disruption.



What the SNOO does

- Gentle rocking
- White noise
- Detects fussing
- Automatically increases motion and sound to soothe, then returns to baseline.

PRIOR WORK

Journal of Obstetric, Gynecologic, & Neonatal Nursing **JOGNN**

ORIGINAL RESEARCH | 2024

Sleep and Mood Among Women With Histories of Depression When They Used a Responsive Infant Bassinet During the COVID-19 Pandemic

Gellasch P, Torraca M, Okun ML.

J Obstet Gynecol Neonatal Nurs. 2024 Jul;53(4):406-415.

Small studies of responsive bassinets suggested benefits for infant sleep, caregiver sleep, caretaking stress, and mood.

WHY WE CHOSE THE SMART BASSINET



- Targeted postpartum sleep disruption
- Directly deliverable to the trainee
- A costly item that many might hesitate to buy themselves
- Supported by a plausible early evidence signal

The smart bassinet fit the package because it targeted a specific postpartum stressor with a directly deliverable support that trainees might otherwise forgo because of cost.

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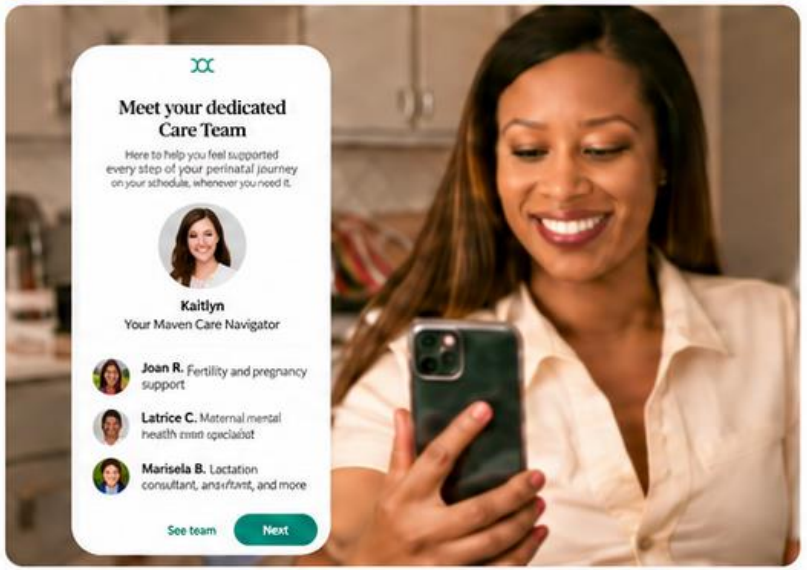
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24/7 Virtual Perinatal Care Reduced Barriers to Support

A portable virtual platform offered around-the-clock access to expert guidance, helping trainees get needed support despite clinical schedules and other barriers to care.

WHAT MAVEN PROVIDED



- 24/7 virtual access
- 30+ specialists
- Pediatricians, lactation, mental health, and more
- Educational classes for infant care and birthing
- Care navigator for scheduling and benefits guidance
- Off-hours appointments

PRIOR WORK

JAMA Psychiatry

Web-Based Cognitive Behavioral Therapy Intervention for the Prevention of Suicidal Ideation in Medical Interns: A Randomized Clinical Trial

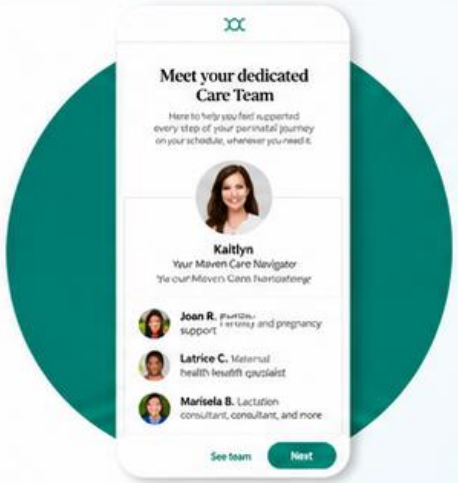
Guille C, Zhao Z, Krystal J, Nichols B, Brady K, Sen S.
JAMA Psychiatry. 2015 Dec;72(12):1192-1198.

Interns with access to web-based therapy were:

- More likely to seek mental health support
- Less likely to endorse suicidal ideation

Proof of concept: Accessible virtual programs can overcome help-seeking barriers in physicians-in-training.

WHY WE CHOSE 24/7 VIRTUAL CARE



Expert support for every step of your perinatal journey — on your schedule.

MAVEN

- Addressed access to expert support during pregnancy, postpartum, and return to work
- Directly deliverable to the trainee
- Low implementation burden for **the program**
- Reduced barriers created by scheduling, geography, and help-seeking
- A scalable support model across institutions

24/7 virtual perinatal care fit the package because it expanded access to expert support in a way that was portable, low-burden, and compatible with the realities of medical training.

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Intervention components map onto multiple burnout domains



Key message: Distinct challenges clustered within shared burnout domains, and the intervention package was designed to target those same domains.

The 4th Trimester Initiative: Study overview

N=156

7 institutions

The 4th Trimester INITIATIVE

Pregnant residents and fellows

Randomized

Usual support

Parental support package


Pump


Bassinet


App


Mentor

What happens when an institution offers this package in the real world?



All participants received a Fitbit Luxe

Sleep tracked through 24 weeks postpartum

Well-being

Burnout, professional fulfillment, postpartum depression

Workforce

Thoughts of attrition, career dissatisfaction

Functioning at work and home

Sleep, medical error, breastfeeding goals

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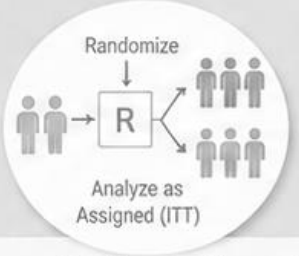
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Primary burnout results, supportive secondary findings, utilization, cost, scalability, and next steps.

Real-world controls don’t stay ‘untreated’



59%

of physician mothers had used a wearable pump at work

If a control participant wanted one, she could buy one.

Colbenson et al, Breastfeed Med 2022

We randomized the offer, not people's lives

Intervention

Parental Support Package provided at no cost



Wearable breast pump



Smart bassinet



24/7 virtual perinatal care



Faculty mentorship

Participants decide what they use and how they use it

Control

Usual environment

Able to purchase wearable pump or smart bassinet themselves

Able to seek mentoring or peer support

Able to purchase a virtual care account

We did not restrict access to these supports

Analysis: intention to treat

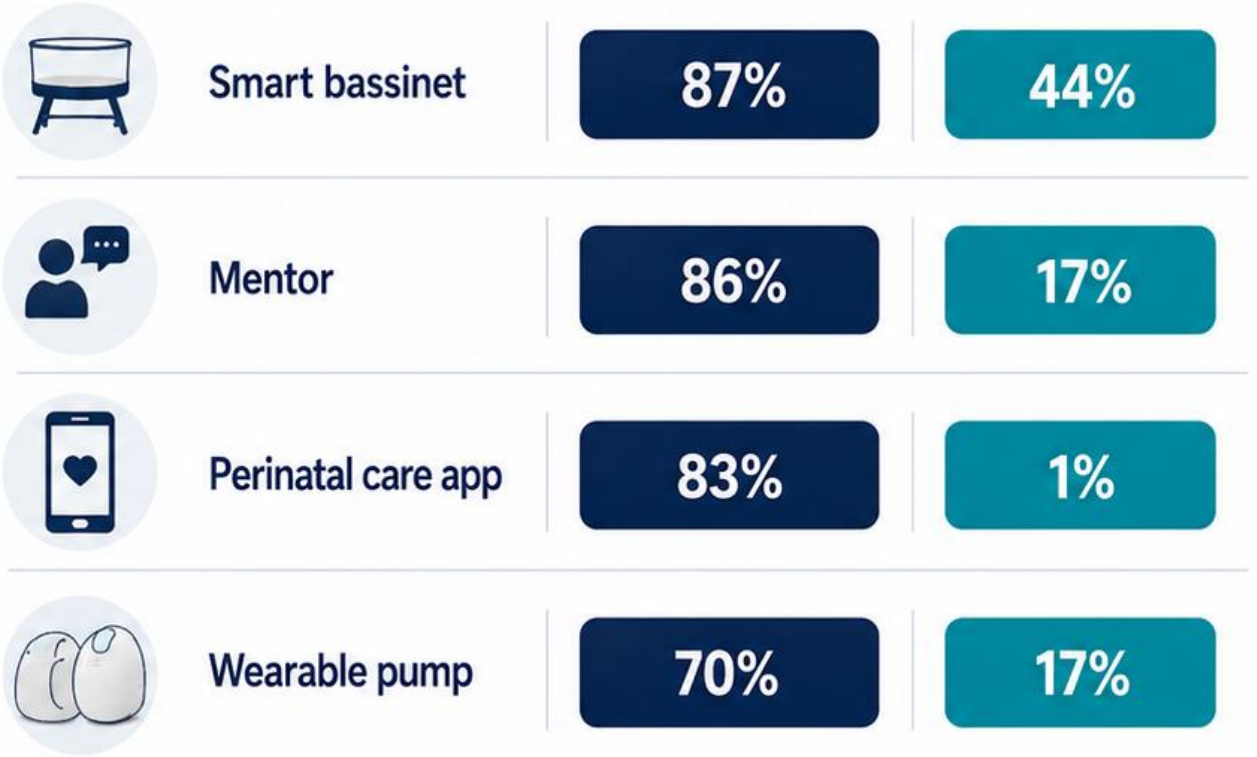
The question: What is the impact of offering this package in real-world training environments?

The messiness happened

Controls still obtained components on their own

62.5%

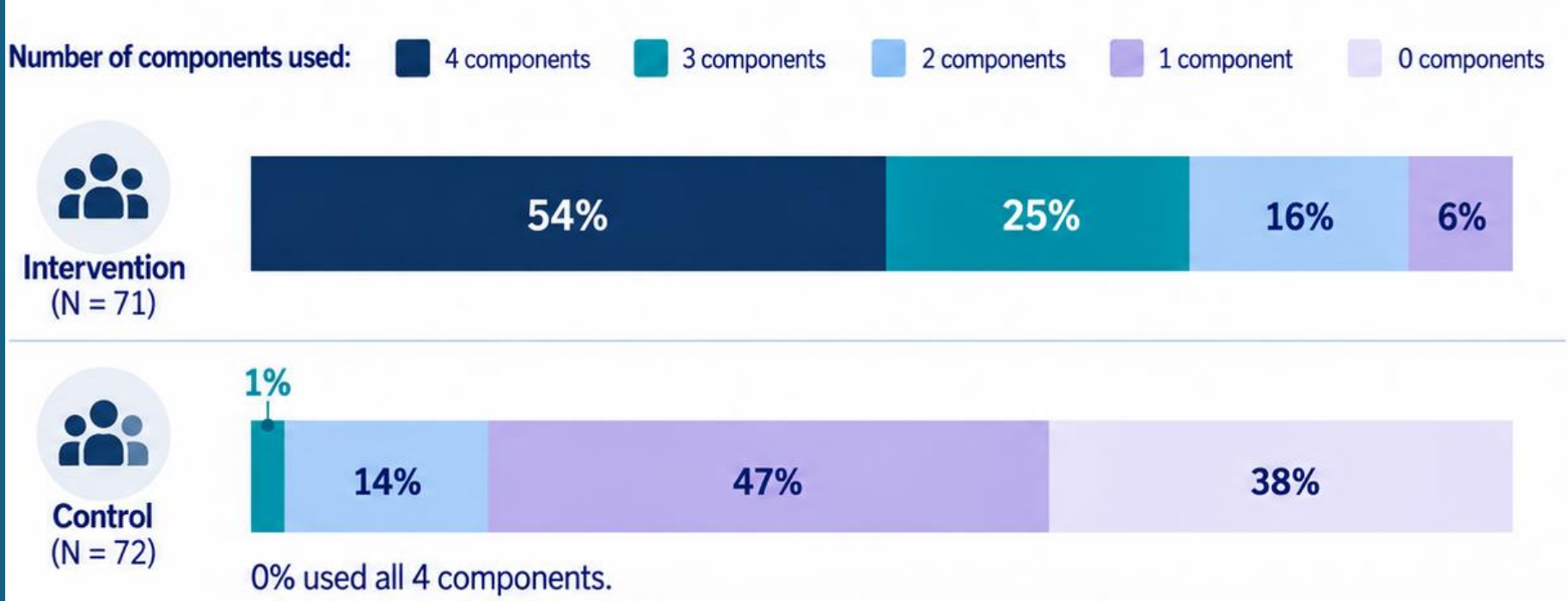
of controls used at least one package component



This was not protocol failure. It reflected real-world behavior.

Participants used the package in different ways

Offering support did not mean mandating every component



79%

of intervention participants used 3 or 4 components

85%

of controls used 0 or 1 component

We did not require perfect adherence. The pragmatic question was whether offering the package improved outcomes.

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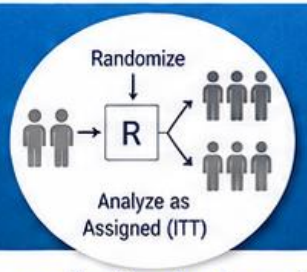
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Primary burnout results, supportive secondary findings, utilization, cost, scalability, and next steps.

We did not standardize parental leave.

Some of the most important postpartum exposures were intentionally allowed to vary.



Leave duration varied

Program support varied

Childcare help varied

From eTable 5:

Actual leave, median (IQR):

PSP 9 weeks (8–12) | Usual support 10 weeks (8–12)

Pragmatic design: let the package operate inside real training environments.

How we handled time-varying factors in the analysis

We distinguished between baseline factors and post-randomization variables that could be influenced by the intervention.

Collected at baseline (pre-randomization)

Included in primary models

Planned parental leave
How much leave trainees intended to take

Perceived program support
How supportive the program was of childrearing

Anticipated childcare support
How much childcare help they expected to have

These factors reflect the environment trainees were entering and are known from the literature to influence childbearing trainee well-being.

Occurred after randomization

Analyzed separately (exploratory models)

Actual parental leave
How much leave trainees ultimately took

Actual program support
The support trainees ultimately received (e.g., schedule flexibility, accommodations)

These factors could have been influenced by the intervention itself (e.g., through a mentor helping a trainee advocate for more leave or support), so we did not adjust for them in the primary analysis.

Pragmatic design: let real-world exposures vary, and avoid adjusting away effects the intervention may have produced.

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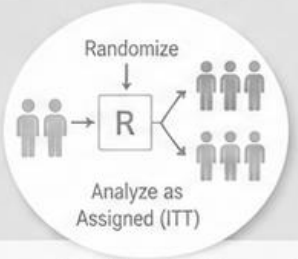
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Primary burnout results, supportive secondary findings, utilization, cost, scalability, and next steps.

Did it work, and could it work in practice?

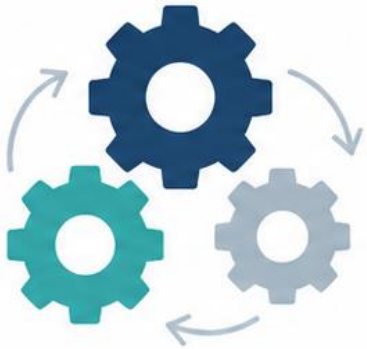
Effectiveness

Did the package improve outcomes?



Implementation

What did we learn about how it functioned in the real world?



The next slides address both questions.

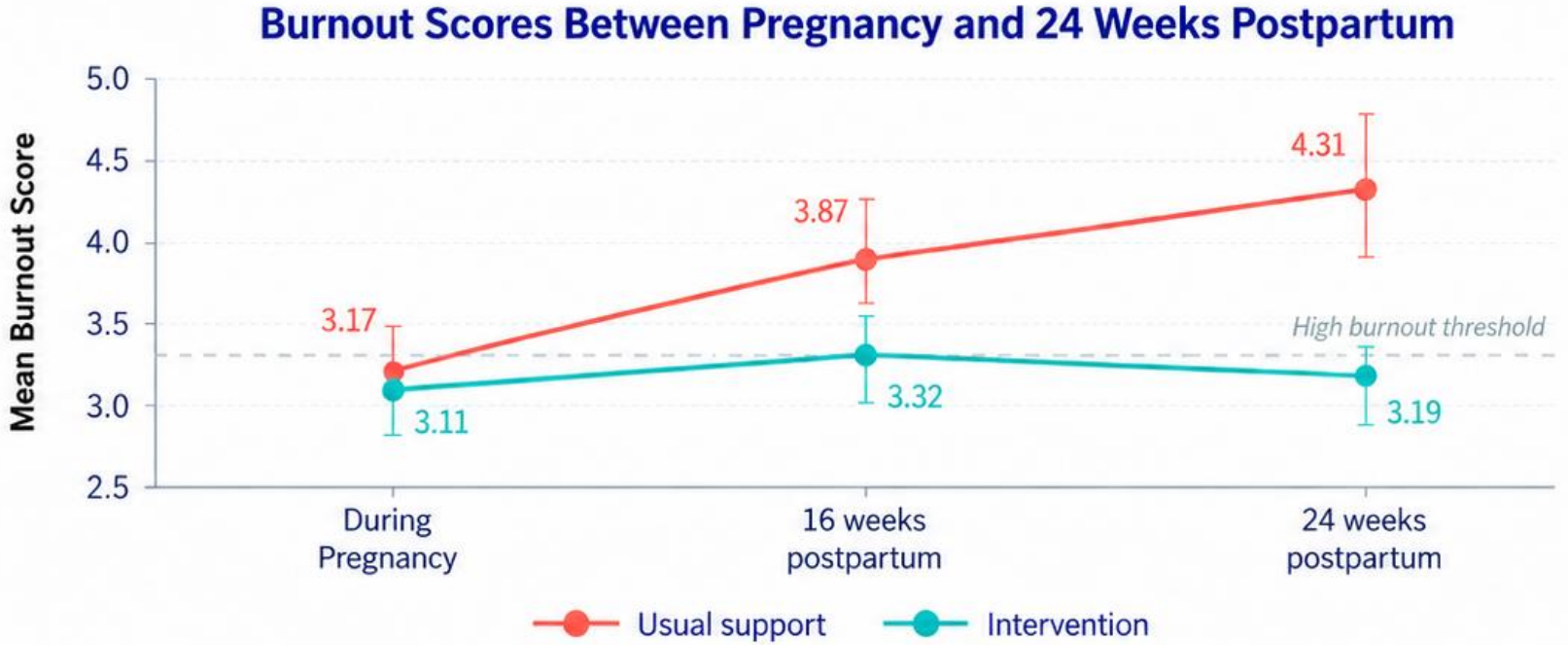
Pragmatic Parental Support to Mitigate Burnout Among Pregnant and Postpartum Trainees

Rubio-Chavez A, Koelliker EL, Askew EA, Shanafelt TD, Landrigan CP, Winn AS, Farid H, Lillemoe KD, Agarwal D, Locascio JJ, Lwin TM, Rangel EL

JAMA The Journal of the American Medical Association

Primary Outcome: Burnout

The intervention mitigated the postpartum rise in burnout



Primary analysis

- Adjusted between-group difference in change: **-0.58**
- 95% CI: **-1.10 to -0.07**
- p = **.03**
- Effect size d = **0.65**

Burnout increased postpartum in usual support but remained stable in the intervention group.

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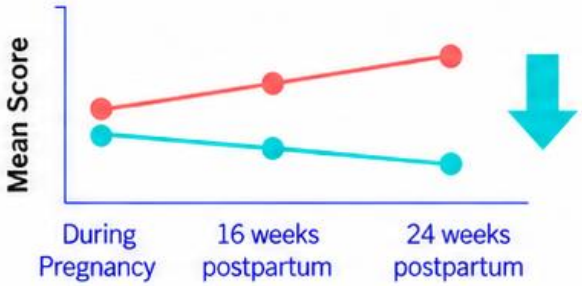
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What Drove the Burnout Effect?

Improvement was driven primarily by interpersonal disengagement

Interpersonal disengagement ↓

Significant

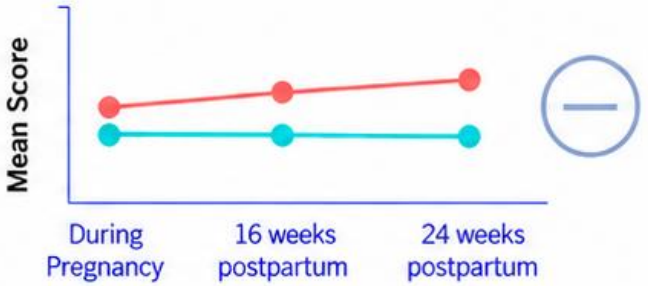


- Adjusted between-group difference: **-0.80**
- p = **.01**
- Effect size d = **0.57**

Lower interpersonal disengagement suggests greater connection and support postpartum.

Emotional exhaustion

No significant difference



- Adjusted between-group difference: **-0.50**
- p > **.15**
- *No significant between-group difference*

The intervention did not appear to substantially change emotional exhaustion.

This pattern suggests the intervention may have worked less by changing workload intensity and more by improving connection, support, and work-life integration.

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Was the effect robust?

Exploratory analyses supported the primary burnout finding.

High burnout moved in opposite directions

+47.1% usual support | **−20.1%** intervention

High burnout increased postpartum in usual support but declined in the intervention group.

Lower odds of high burnout at follow-up

OR 0.19

Participants in the intervention group were substantially less likely to meet the high-burnout threshold at follow-up.

The finding persisted after accounting for sleep

Adjustment for sleep-related impairment only modestly attenuated the burnout effect.

This suggests that sleep alone did not explain the between-group difference in burnout.

Together, these exploratory analyses reinforced the conclusion that the parental support package mitigated postpartum burnout.

Impact of Sleep and Fatigue on Self-Reported Medical Error

Objective sleep



Similar between groups

No clear difference in wearable-measured sleep

Sleep-related impairment

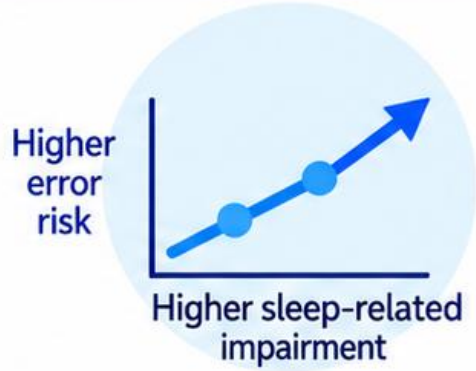


-2.5 points

PROMIS sleep-related impairment

Lower with support package

Sleep-related impairment and error



+12% odds per point

Higher sleep-related impairment = higher odds of self-reported error

Self-reported medical error



OR 0.43

Lower odds with support package

KEY MESSAGE

Subjective fatigue tracked with error better than objective sleep, and the intervention improved fatigue and error.

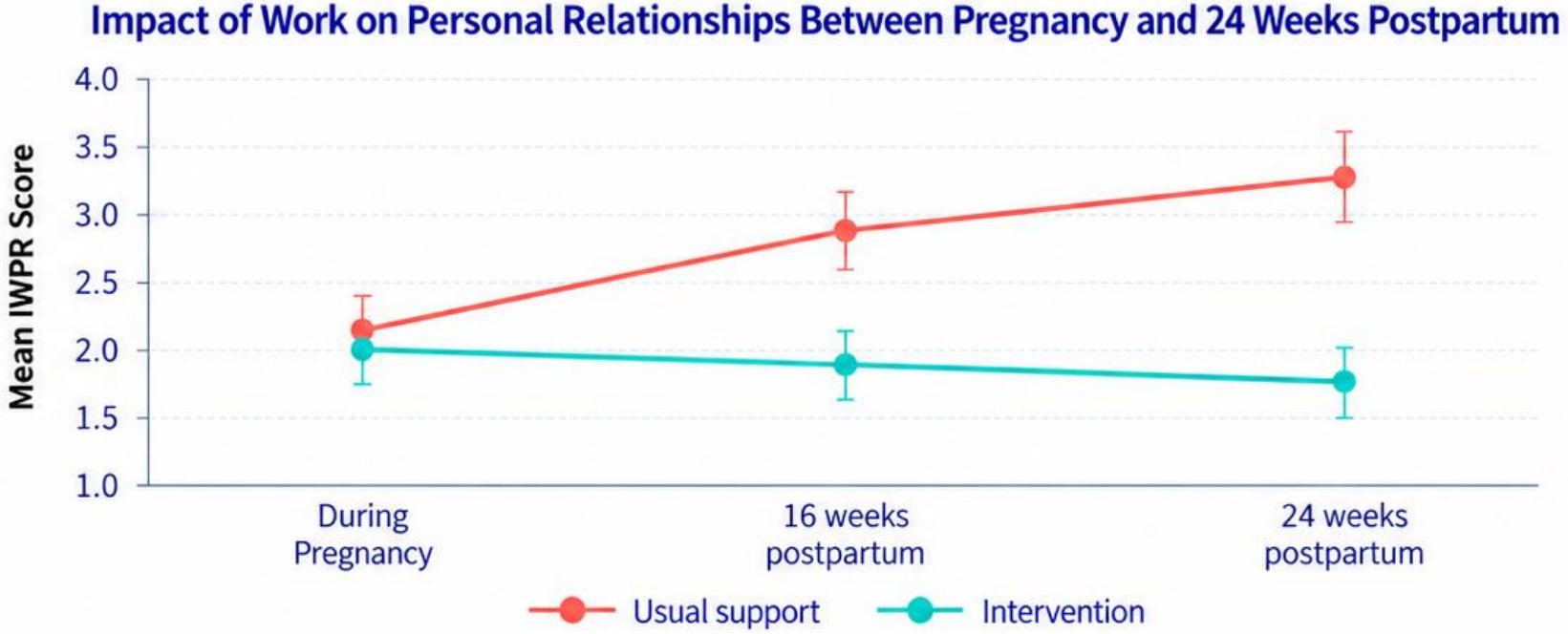
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Impact of Work on Personal Relationships

The package also reduced work-related relationship strain



Primary analysis

- Adjusted between-group difference in change: **-0.90**
- p = **.04**
- Effect size d = **0.61**

Work-related relationship strain worsened postpartum in usual support but was reduced in the intervention group.

SECONDARY OUTCOMES

Benefits were not uniform across all well-being domains

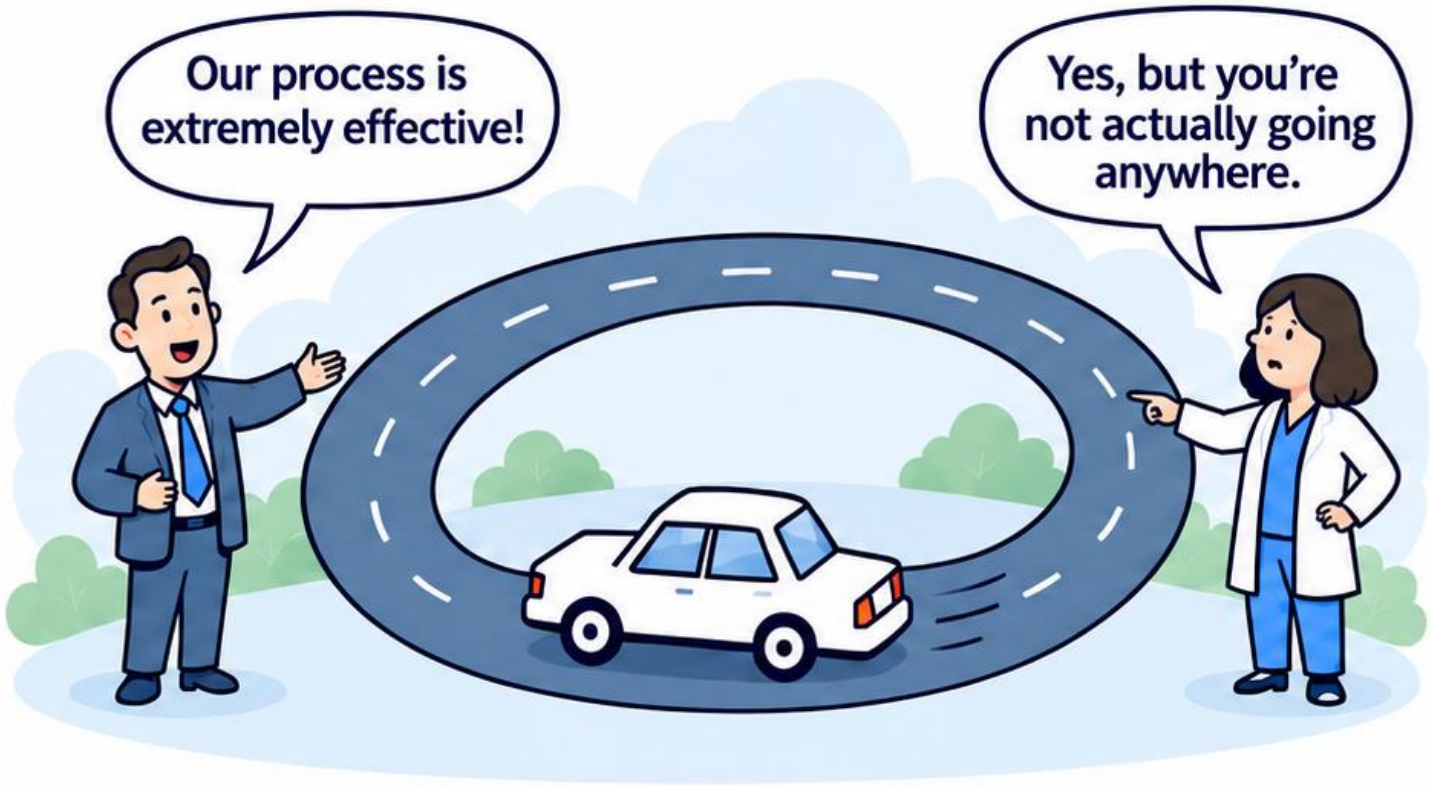
Several prespecified secondary outcomes trended favorably, but none reached statistical stgnificance.

Outcome	Adjusted between-group difference in change	p value
Organizational and personal values alignment Values alignment	**0.63**	.13
Professional fulfillment SPFI professional fulfillment	**0.28**	.24
Career dissatisfaction Binary outcome	**10.1** (3.12–32.46)	.26

All point estimates favored the intervention, but none of these prespecified secondary outcomes reached statistical significance.

But effectiveness was only half the question

To understand what the package meant in practice, we also asked how participants actually experienced it.



What we learned already

- Substantial crossover signaled demand
- Participants did not use the package uniformly
- Package cost: ~$2,300 per trainee

Package cost:
~$2,300
per trainee

Estimated annual cost of physician burnout:
~$7,600
per physician

Favorable ROI, but up-front affordability can still be a barrier.

What we needed to understand next

- Which components mattered most to participants?
- Did different components solve different problems?
- Were there unintended consequences?

Next: qualitative interviews

How participants experienced the package, and what that tells us about implementation.

QUALITATIVE RESULTS

Qualitative interviews showed that participants experienced different components in different ways

Findings from postpartum qualitative interviews with 55 trial participants



Mentorship

Connection, advocacy, validation

- Helped navigate training
- Provided an advocate
- Reduced feelings of isolation



Smart bassinet

Improved infant sleep, reduced fatigue

- Helped both infant and parent sleep
- Made return to work more manageable



Wearable pump

Flexibility, but not a substitute for protected breaks

- Made pumping more feasible in clinical settings
- Sometimes reinforced stigma around lactation breaks
  - Some faculty asked why trainees couldn't just use a wearable pump instead of stepping away



Virtual perinatal care

Access despite inflexible schedules

- Timely, convenient support for pregnancy and postpartum
- Helped address concerns outside of work hours

> *"It's just invaluable to have a person you can turn to who's been through that experience and is willing to spend their own personal time helping you. I think that support is something that is very hard to mimic in any other relationship."*
>
> – Plastic surgery trainee, intervention group

> *"[The parental support package] was so impactful. Probably in more ways than I even know. I felt so much more supported... I knew I had this support system behind me focused on my pregnancy and postpartum journey... that was impactful on my mental health."*
>
> – PM&R trainee, intervention group

Beyond the individual components, interviewees described feeling seen, supported, and valued.

Next step: optimizing the support package

From showing that the package works to understanding what is most worth carrying forward.

4-component parental support package



Mentorship



Smart bassinet



Wearable pump



Virtual perinatal care

Optimize the package

1. Which individual components contribute most to benefit?
2. Which components appear most promising to carry forward?
3. Can lower-cost, lower-burden combinations preserve benefit?



Goal: identify the components most worth carrying forward **while improving affordability and scalability.**

Questions?