BMJ Open

The kindness COVID-19 toolkit: a mixed methods evaluation of a workshop designed by doctors in training for doctors in training.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-060575
Article Type:	Original research
Date Submitted by the Author:	04-Jan-2022
Complete List of Authors:	Ward, Madeleine; Monash University, Obstetrics & Gynaecology; Monash Health, Women's & Newborn Crinall, Karen; Crinall Consulting McDonald, Rebecca; Monash Health, Women's & Newborn; Monash University, Obstetrics & Gynaecology Crinall, William; Crinall Consulting Aridas, James; Monash Health, Women's & Newborn; Hudson Institute of Medical Research, The Ritchie Centre Leung, Cheryl; Monash Health, Women's & Newborn Quittner, Danielle; Monash Health, Women's & Newborn Hodges, Ryan J; Monash Health, Women's & Newborn; Monash University, Obstetrics & Gynaecology Rolnik, Daniel ; Monash Health, Women's & Newborn; Monash University, Obstetrics and Gynaecology
Keywords:	COVID-19, OBSTETRICS, QUALITATIVE RESEARCH

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Title:

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Authors:

Madeleine Ward[1,2] (0000-0001-6501-7151), Karen Crinall[3], Rebecca McDonald[1,2], William Crinall[3], James Aridas[1,4], Cheryl Leung[1], Danielle Quittner[1], Ryan J Hodges[1,2], Daniel L Rolnik[1,2]

Addresses:

1. Department of Obstetrics and Gynaecology, Monash Health, Clayton, VIC, 3168, Australia
2. Monash University, Clayton, VIC, 3168, Australia
3. Crinall Consulting, VIC, Australia
4. The Ritchie Centre, Hudson Institute of Medical Research, Clayton, VIC, 3168, Australia

Corresponding author:

Madeleine C Ward

Monash Health

246 Clayton Road

Clayton, 3168, Victoria, Australia

madeleine.ward@trainee.ranzcog.edu.au

Contribution statement:

All listed authors have contributed to the manuscript and meet authorship criteria, without the exclusion of others.

Conflict of interest statement:

The authors have no competing interests to declare.

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Madeleine Ward[1,2], Karen Crinall[3], Rebecca McDonald[1,2], William Crinall[3], James Aridas[1,4], Cheryl Leung[5], Danielle Quittner[6], Ryan J Hodges [2,7], Daniel L Rolnik[1,6]

1. Obstetrics and Gynaecology Registrar, Monash Health, Clayton, VIC, Australia
2. Monash University, Clayton, VIC, Australia
3. Consultant, Crinall Consulting, VIC, Australia
4. The Ritchie Centre, Hudson Institute of Medical Research, Clayton, VIC, Australia
5. Director of Training Obstetrics and Gynaecology, Monash Health, Clayton, VIC, Australia
6. Obstetrics and Gynaecology Consultant, Monash Health, Clayton, VIC, Australia
7. Program Director, Women's & Newborn, Monash Health, Clayton, VIC, Australia

Corresponding author: Dr Madeleine Ward
Monash University Wellington Road, Clayton, 3800, Victoria, Australia.
T: 03 9905 4000 E: madeleine.ward@monash.edu

Contribution statement: MW, RM, JA and DR contributed to the study design and implementation. Quantitative data was collected by JA, RM and MW, and analysed by DR, RM and MW. Qualitative data collection and analysis was conducted by KC and WC. MW oversaw the compilation of the first draft of the manuscript. All listed authors contributed to manuscript and meet authorship criteria, without the exclusion of others.

Abstract

Objectives The impact of a coronavirus disease (COVID-19) specific professional development program on the wellbeing of obstetrics and gynaecology (O&G) doctors in training (DiT) working during the pandemic.

Design A mixed-method evaluation of a single group pre-post test design study.

Setting Melbourne, Australia between September 2020 and April 2021.

Participants 55 O&G DiT working across four healthcare sites of a major tertiary hospital in Victoria, Australia, were included in the program.

Interventions The delivery of a co-designed peer-to-peer (P2P) program, which identified and addressed the wellbeing goals of O&G DiT. Three interactive workshops were run alongside the implementation of a number of participant-led wellness initiatives.

Main outcome measures Repeated measures analysis of World Health Organization Wellbeing Index (WHO-5) and Copenhagen Burnout Innovatory (CBI) scores across three time points during the program. Multilevel generalised linear mixed effects models with random intercept were fit to the data, both in the entire population ("intention-to-treat") and restricted to those who attended the workshop ("per protocol" analysis). Participatory experiences and program learnings were captured using the Most Significant Change (MSC) technique, which included inductive thematic analysis.

Results We demonstrated an overall 31.9% improvement in wellbeing scores (p=0.006). The MSC evaluation captured a shift in workplace culture as a result of the program, with improvement across the domains of connection, caring, communication, confidence and cooperation.

Conclusions We have successfully used a mixed-methods approach to contextualise a productive program to improve the wellbeing of COVID-19 frontline healthcare workers.

Keywords Mixed methods evaluation, coronavirus disease (COVID-19) pandemic, Zoom, wellbeing program, Pandemic Kindness Movement, doctors in training, obstetrics and gynaecology, junior medical officers, healthcare worker, most significant change technique.

Article Summary

Strengths and limitation of this study
- We provide a co-designed and participant-led pandemic specific educational program which prioritises, problem solves and tracks the indicators of burnout in frontline healthcare workers - Our program is evaluated using a mixed-methods analysis, enhancing the interpretation of outcomes and adding valuable information about the impact, acceptability and utility of our intervention - We pilot a wellbeing workshop model and evaluation strategy with promising utility in future healthcare and non-health settings

Introduction

The novel coronavirus disease (COVID-19) pandemic has had an unparalleled impact on the provision of healthcare, resulting in significant physical and emotional burden on those accessing and servicing the acute hospital setting.[1,2] It has created further pressure on an

already vulnerable group of doctors with additional risks from exposure to an infectious disease, reduced resources and high workload.[1,3]

Burnout is a recognised occupational hazard for healthcare workers and encompasses emotional exhaustion, withdrawal from patients and loss of job satisfaction.[4] Ensuring the health of workers is vital for the delivery of a high quality service, with healthy workers demonstrated to provide better customer relations, have more positive attitudes, and be more enthusiastic. [3,5] In comparison to other professionals, doctors are ten-times more likely to suffer from psychological distress, especially those under the age of thirty.[6,7] These findings are not isolated to the Australian medical workforce, with 69% of USA healthcare workers reporting workplace stres and 37% of UK doctors requiring additional care due to burnout [4]. More than a decade ago a national report highlighted the significant distress of Australian doctors in training (DiT) with less than 30% satisfied with their career, over half (54%) loosing compassion for patients and more than two thirds (69%) having burnout [8]. Obstetrics and Gynaecology (O&G) DiT work long hours and shift work, which are known to contribute to dissatisfaction and reduced wellbeing, as well as occupational stress, burnout and mental health issues.[3]

Despite safety and quality healthcare indicators being drivers for accountability there is a failure to recognise the need to support the wellbeing of healthcare workers.[7] In recognition of the immediate risk to the wellbeing of the Women's Health DiT group and associated impacts on health service provision we aimed to provide an appropriately resourced, efficient and effective COVID-19 pandemic-specific professional development program focused on improving the wellbeing of O&G DiT. The program was co-designed by the O&G DiT group and delivered via a peer-to-peer (P2P) teaching model, and aimed to:

1. Assess the wellbeing and symptoms of burnout among the Monash Women's DiT in O&G.
2. Provide immediate and practical tools and strategies to enhance the wellbeing of Monash Women's DiT working during the COVID-19 pandemic.
3. Generate an evidence base, informed by qualitative and quantitative data, to advise future implementation.

Monash Women's, a major tertiary hospital in Victoria, Australia has been a leader in the implementation of COVID-19 strategic management plans, policies and procedures with the safety and wellbeing of staff, patients and the community at the forefront.[9]

Methods

Here we list the steps involved in the P2P pilot program development, including the details of the co-design processes followed. The integration of a mixed-method analysis is explored, an approach which takes advantage of the considerable impact qualitative research methods can have on reviewing health interventions.[10] A quantitative evaluation was conducted of the World Health Organization Wellbeing Index (WHO-5) and Copenhagen Burnout Innovatory (CBI) measures that were administered prior to and at multiple time points following the program.[11,12] Qualitative analysis utilising the Most Significant Change (MSC) technique, is also described and the key outcomes listed.

Research ethics approval

The project was funded by the Monash Health Foundation and granted ethics approval from Monash Health Human Research Ethics Committee (QA/68545/MonH-2020-230841(v2)). Within the manuscript all details of the study are accurately and transparently provided in an honest account of the study.

Participants

All 55 Monash Women's doctors in training (DiT) working across four sites – one tertiary and three secondary hospitals (Monash Medical Centre, Dandenong District Hospital, Moorabbin Health and Casey Hospital) were invited to participate in the study. Our study was a pilot project with a convenience sample size without a formal power calculation. Recruitment was maximised via advertising utilising group email. An introduction and orientation session was held with opportunity to complete recruitment at this time, and reminder emails were sent to increase uptake. Recruitment at the beginning of the first workshop also took place. Inclusion criteria included being a current O&G DiT who were both available and willing to attend the workshops and complete the questionnaires.

Patient and public involvement

The '*Monash Women's leading kindness COVID-19 toolkit'* program was developed using a co-design process. Three online workshops, each of three-hours duration, were delivered by

DiT to their peers during protected teaching time on 17 September 2020, 24 September 2020 and 5 November 2020. This model was selected to maximise positive impacts and enable rapid implementation of change.[13] It is also a familiar style of learning given its similarity to the traditional 'journal club' style of medical education frequently used in the training of Australian medical doctors.

The intervention

Workshop topics were modelled on the 'Pyramid of needs', for health worker wellbeing (Figure 1), (based on Maslow's hierarchy of needs),[14] and covered six topic areas: basic needs, safety, love and belonging, esteem, contribution and leadership. Workshop content dissemination was maximised with recordings, webmail links and online communities. In keeping with the co-design approach, participant-led initiatives were encouraged and developed during the workshop program, and supported advocating for personal solutions.

Figure 1 Pyramid of Needs

An overarching self-selected group of senior DiT, known as workshop 'champions', initiated the project, formulated goals (Figure 2) and directed activities in line with those promoted by Beyond Blue 'Protecting your mental health and wellbeing as a healthcare worker'.[15] Monash Women's executive leaders were also engaged to participate and act on organisational level solutions. Together these contributed to a toolkit being developed which incorporated workshops, goals, activities and resources. Activities included the provision of a drink 'hydration' station to encourage breaks; the creation and display of posters articulating the main workshop points; improvements to the doctor office space; social online sessions by Zoom Cloud Meetings (Zoom Video Communications, San Jose, CA, USA); and a team social media app. Further information on the program, including a workbook and templates can be found in resources: 'Monash Women's Leading Kindness COVID-19 Toolkit Pilot Project Most Significant Change Evaluation Report';[16] 'Monash Women's Leading Kindness COVID-19 Toolkit Pilot Project Quantitative Evaluation Report', [17] and 'Start up: A Kindness COVID-19 Toolkit'.[18]

Figure 2 Goals of the 'Monash Women's leading kindness COVID-19 toolkit'

The evaluation strategy

Quantitative analysis

The CBI [12] and WHO-5 [14] questionnaires, both well-validated and standardised, were employed to evaluate the pre-existing wellbeing and symptoms of burnout in the cohort O&G DiT (September 2020, timepoint one). Both were repeated at timepoint two (November 2020) and at timepoint three, six months following the completion of the workshop (April 2021). Questionnaires were delivered and secured electronically via the online data collection tool, Qualtrics (Qualtrics, Provo, UT, USA), with surveys labelled with an anonymous but memorable code, created by the participant, to preserve confidentiality.

The WHO-5 is a standardised questionnaire, which asks five questions focused on wellbeing in the preceding two-week time period (Appendix 1). A total score of less than 50 is considered to represent reduced wellbeing.[11] The CBI assesses the load of personal, work and patient related factors on burnout, with its benefits being a readily available and brief evaluation tool. A score of 25-50 indicates an intermediate level of burnout, and greater than 50 a high level of burnout.[19]

Statistical analyses were performed in Stata 16.1.(StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC). To compare the CBI and WHO-5 scores after exposure to the program (timepoints two and three) with those before its implementation (timepoint one) accounting for the repeated measures design, multilevel generalised linear mixed effects models with random intercept were fit to the data, both in the entire population ("intention-to-treat") and restricted to those who attended the workshops ("per protocol" analysis). In these models, the measurements timepoints were treated as fixed effects and participants were treated as random effects. The assumptions of linear additivity and homogeneity of the residuals were assessed by inspection of residual versus fitted plots. Effect estimates are reported as the mean difference with 95% confidence intervals, and p-values below 0.05 were considered statistically significant.

Qualitative analysis

Qualitative evaluation utilising the MSC technique was chosen to gain insight into participants' experience of the personal and professional impacts of the toolkit. Story gathering interviews took place via Zoom sessions between 8 December 2020 and 4 January 2021. Nine stories of change were collected from interviews that lasted between 20 and 40 minutes. To ensure rigour and impartiality external expertise in qualitative analysis was engaged. MSC was chosen

because it seeks to learn about participants' perceptions of program impacts by evaluating their stories of significant change, and thereby complemented the program's participatory principles: co-design, peer leadership and P2P learning. MSC was also selected because of its focus on 'what works well and how to do more of what works'.[20]

Consistent with the MSC technique, the evaluation incorporated three main steps:

1. Collection of Significant Change stories.
2. Selection of the Most Significant Change story, and identification of key themes.
3. Documenting and communicating the Most Significant Change story and key themes.

The MSC technique involves a hierarchical selection process which narrows the data down to one story representing the most significant change. A stakeholder panel consisting of trainees and supervisors, as well as interview participants who were contributors of stories of change, undertook a two-tiered process involving the selection of one significant story from a total of nine stories (Figure 3).

Figure 3 MSC selection process

To gain a comprehensive picture of the range of significant changes experienced by participants an inductive analysis of all nine stories was conducted to capture emergent themes. This methodology is further discussed in other publications. [16,21,22]

Results

Participants

Forty-six (83.6%) DiT completed the initial WHO-5 and CBI at timepoint one. Seventeen DiTs, including residents and registrars, attended at least one of the three live workshops. All 55 DiT were exposed to the initiatives of the toolkit, however specific details of their uptake are unknown. Following the completion of the workshops (timepoint two), 27 responses were collected, of whom 59.3% (n=16) were workshop participants (live or recorded viewing). At timepoint three 11 responses were collected, with 63.6% (n=7) being participants of the workshops.

Quantitative analysis: CBI and WHO-5

Figure 4 Repeated measures CBI and WHO-5 scores for all and restricted to those who participated in the 'Monash Women's leading kindness COVID-19 toolkit' workshops.

Copenhagen Burnout Inventory

Among all DiT (those who participated in the workshop and those who did not), there was a mean reduction of 2.0 points (95% CI: -7.4 to 3.3) at timepoint two compared to timepoint one, although this reduction was not statistically significant (p = 0.454). There was a mean reduction of 6.8 points (95% CI: -14.4 to 0.7) at timepoint three compared to timepoint one, demonstrating a trend towards statistical significance (p = 0.077). Similarly, among those who participated in the workshop, there was a mean reduction of 0.3 points (95% CI: -6.8 to 6.2) at timepoint two compared to timepoint one, although this reduction was not statistically significant (p = 0.935). There was a trend towards statistical significance (p = 0.086) at timepoint three compared to timepoint one with a mean reduction of 8.2 points (95% CI range: -17.5 to 6.2).

WHO wellbeing index

Among all participants there was a statistically significant mean increase of 10.5 points (95% CI: 3.3-17.7, p=0.006) at timepoint two compared to timepoint one, and a statistically significant mean increase of 14.9 points (95% CI range: 0.5-29.3, p=0.006) at timepoint three compared to timepoint one. Analysis restricted to those who participated in the workshop showed a mean increase of 9.2 points that trended towards statistical significance (95% CI: -0.2 to 18.5, p = 0.054) at timepoint two compared to timepoint one, and a significantly higher WHO score at timepoint three, with a mean increase of 16.4 points (95% CI range: 3.2 to 29.7, p = 0.015) at timepoint three compared to timepoint one.

Qualitative Analysis

The MSC story

The selected story 'Team cohesiveness' was contributed by a junior O&G DiT workshop participant. It was chosen by the panel because it described how the COVID-19 toolkit pilot brought about cultural change and fostered a sense of kinship by enabling basic needs to be met, breaking down hierarchical barriers within the Monash Women's Health team and building team cohesiveness multi-directionally.

"With the introduction of the Wellbeing program there was a more organised sense of looking out for each other… A highlight was senior clinicians telling their own stories…Witnessing their fears and concerns, and their approaches to challenges makes you more impressed by their achievement, you feel like challenges are more approachable, the steps ahead are more attainable...The program was also an opportunity to address the things that make a cohesive team, that make us all better together."

Themes

Significant changes linked to five interconnected themes (Figure 5) were woven throughout the nine stories and encapsulated in the most significant change story selected by the panel.

Connection: Communication played an important role in fortifying connections.

'Hearing others talk about their experiences and feelings of not being okay and sharing my experiences and feelings. That made me feel more connected and less alone'.

Caring: The workshop on meeting basic needs not only changed the way trainees thought about self-care and meeting their own basic needs, they also began to care more for each other.

'After the workshop people were asking, "Have you had water this morning? Have you had enough to eat?"

Communication: One story described the pilot program as having created a 'space to talk' which allowed trainee doctors to 'hear each other'.

Confidence: DiT were more confident about their capacity to be leaders and to make a difference in their workplace.

'The most important change brought about by the wellbeing program for me was recognising my agency. I learned there were changes I could make.'

Cooperation: Participants observed the shift to more cooperative work practices.

'More than before the whole team stepped up to help each other make it through the day together'.

Figure 5 Themes revealed by stories which came together to shift the workplace culture.

Discussion

'The difference that made a difference.' [22]

This study piloted a pandemic educational program to improve wellbeing designed by and for a group of 55 O&G DiT at a major tertiary hospital in Victoria, Australia during the 2020 COVID-19 pandemic. We tracked the indicators of wellbeing and burnout with collection of surveys before (n=46 and after (n=27 and 11) the implementation of three workshops, which were one component of a collection of initiatives that comprised a toolkit of resources. Nine workshop participants were interviewed about their most significant experiences of change resulting from the program. We demonstrated an overall 31.9% improvement in wellbeing scores. The MSC evaluation identified an overall positive shift in workplace culture associated with change across five domains: connection, caring, communication, confidence and cooperation.

The impact of COVID-19 on the safety and wellbeing of healthcare workers is well documented.[2,23-5] Ellis et al.[2] reported an increase in surgical error due to the combined effects of COVID-19 on doctors' sleep hygiene, concerns regarding infection exposure and the burden of personal protective equipment restricting movement and communication. However, despite well-known risks to DiT and an urgent call for interventions,[6,26] there has been a lack of validated programs aimed at improving their wellbeing.[7,27]

During the third month of the second Victorian COVID-19 pandemic lockdown, which lasted 112 days from the 6th of July 2020 to the 26th of October 2020,[28] we observed that Monash Women's DiT were experiencing significantly reduced wellbeing (mean score 46.7) and intermediate levels of burnout (mean score 48.1). DiT working in O&G are responsible for providing care across a range of clinical areas within the health service site, including the emergency department, outpatient clinics, inpatient wards, operating theatres, and birthing suites. In a recent survey obstetricians and gynaecologists were amongst the highest at risk of physician burnout.[29] Anticipating that the added workload generated by a pandemic situation would pose additional risk to the wellbeing of O&G DiT is not unwarranted, with Ochsmann et al.[30] identifying strain levels as directly related to overtime worked. The provision of safe

care also depends on effective communication with patients, their families and across multidisciplinary teams spanning all levels of the organisational structure. These multi-dimensional care and communication challenges have also been demonstrated to increase risk for emotional and physical fatigue. [31]

The 'Monash Women's COVID-19 leading kindness toolkit' program demonstrated a 31.9% improvement in the wellbeing index for all DiT participants, and safeguarded against worsening burnout symptoms. Those who attended a component of the integrated workshops experienced slightly greater impact (35.5%) on wellbeing over time. The overall achievement of the pilot project, as expressed by participants in their stories of change, was a shift to a more caring and supportive workplace culture. Junior and senior DiT felt more connected as colleagues and were more confident about advocating for change and communicating with one another about their work. The impact of workplace friendships has been shown to be inversely related to workplace stress with healthcare workers relying most heavily on strong peer-support, sharing with senior staff and supportive social networks when facing a crisis.[3] The P2P style of our program was highlighted as a strength by participants. This is consistent with the finding of Chanchlani et al.[6] who evaluated a P2P mentoring program and demonstrated an improved sense of community and support. Similarly, Walton et al.[9] identified the important role of P2P interactions in the acquisition of complex non-technical skills.

Based on our experience in this initiative, we strongly advocate for a mixed-methods approach in the evaluation of health care programs. Triangulating qualitative and quantitative methods enhances interpretation of outcomes, and provides valuable information about the impact, acceptability and utility of interventions.[12,31] This integrative approach utilises the complementary capacities of quantitative research in defining measurable variables and qualitative research in investigating complex social constructs.[12] Exploring reasons for participant satisfaction or dissatisfaction, lack of adherence and causes of conflicting outcomes in different population groups are examples of the way qualitative analysis can enhance quantitative findings.[32] Despite growing recognition of the value of mixed-method designs there remains a lack of published medical studies employing a dual-analysis approach.[12] Supported by Lewin et al.[31] who conducted a review of the Cochrane register and identified just one third undertook a combined quantitative and qualitative analysis. Recognised barriers to mixed-method designs in medical research include the need for adequate resourcing, the

time-consuming nature of the research process and difficulty accessing appropriately experienced qualitative researchers.[31]

Implications and limitations

The program was enthusiastically welcomed, and our findings attest to the benefits received by participants. The triangulation of quantitative and qualitative results demonstrates DiT were provided with tools to reduce burnout and improve wellbeing. Although our results suggest an improvement in burnout over time, this effect did not reach significance. Given the small numbers, our study may have been underpowered to detect a significant improvement in burnout. Alternatively, the program may have limited impact on improving burnout. However, given the entire cohort remained within the intermediate burnout category (score 25-50), our findings support the program's success in protecting against worsening burnout during the pandemic.

The results of this pilot study are limited by the small sample size and self-imposed limitation on the collection of participant characteristics in order to preserve anonymity. A key component of the MSC technique is sharing personal stories. This presents challenges for maintaining confidentiality. The sample size and close working relationships meant maintaining anonymity could not be guaranteed. We addressed this by disaggregating stories, and by ensuring participants were informed that they may be identified.

Over the last few years, there has been a greater focus on the nurturing of emotional intelligence. Many of these efforts have involved self-directed learning, action coaching and formalised mentoring programs.[33] These attempts have faced substantial system-based obstacles and have, at times, paradoxically penalised the individual doctor for failing to self-care. Doctors in training are a highly goal motivated group, yet messages that a lack of resilience, weakness, and laziness typify those who succumb to these stressors is enduring.[3,7,33] The harm from erroneous messages sent through labelling doctors as super-humans is also well documented; often as a gesture of thanks this culture lends itself to messages of the need to 'tough it out'.[34] Together, these run the risk of adding to the misconception that seeking help is a sign of weakness, failure and not having what it takes to survive the rigors of medical training.

In co-designing our program, we were able to create a system of resources, which were meaningful and useful. In combination with a solid commitment from the organisation to support and see through the delivery of the program, we effectively created a cultural shift and built capacity with a lasting impact for our team. The provision of programs with a directive to protect and prevent healthcare workers from burnout is desperately needed. Interventions must be directed and targeted, recognising time constraints, transient working locations and competing demands. Additionally, their evaluation is imperative.[7] It is vital that doctors feel safe to seek help, and more importantly administrators need to identify, track and monitor the wellbeing of employees and act well before crisis point is reached [35].

We have successfully used a mixed-methods approach to contextualise a productive program to improve the wellbeing of COVID-19 frontline healthcare workers. We hope the evidence generated from our program contributes to informing the implementation of future programs within other healthcare groups and settings.

Funding

The 'Monash Women's leading kindness COVID-19 toolkit' wellbeing program and its evaluation was funded by Monash Health Foundation grant. The program and analysis were undertaken independently and without influence from the funding body.

Acknowledgments

The Pandemic Kindness Movement was a vital resource for inspiration and implementation of the program. We would like to thank the A/Prof Jane Munro along with all the clinicians and experts who contributed and curated this wonderful collection of information in such a user friendly and available format.

We would like to acknowledge the overarching guidance provided by A/Prof Jacqueline Boyle and A/Prof Arunaz Kumar who were instrumental in the planning of the project and evaluation processes.

We would also like to extend our gratitude to A/Prof Beverly Vollenhoven, Dr Mark Tarrant, Dr Risha Bhatia and A/Prof Arunaz whose participation and feedback were crucial to the success of the evaluation.

We would also like to thank the Monash Women's O&G DiT who co-designed this pilot project along-side us. Especially to those who took the time to participate, present and provided vital feedback during a time in which they were most under the pump. Without your efforts there would be no program to report on.

Licence agreement

Competing interest

"All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: support from Monash Health Foundation COVID-19 Research grant for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work." (BMJ Author Guidelines, 2021)

Data sharing

We commit to undertaking all reasonable requests to share relevant data.

Figures

Figure 1: Pyramid of Needs

Figure 2: Goals of the 'Monash Women's leading kindness COVID-19 toolkit'

Figure 3: MSC selection process

Figure 4: Repeated measures CBI and WHO-5 scores for all and restricted to those who participated in the 'Monash Women's leading kindness COVID-19 toolkit' workshops.

Figure 5: Themes revealed by stories which came together to shift the workplace culture.

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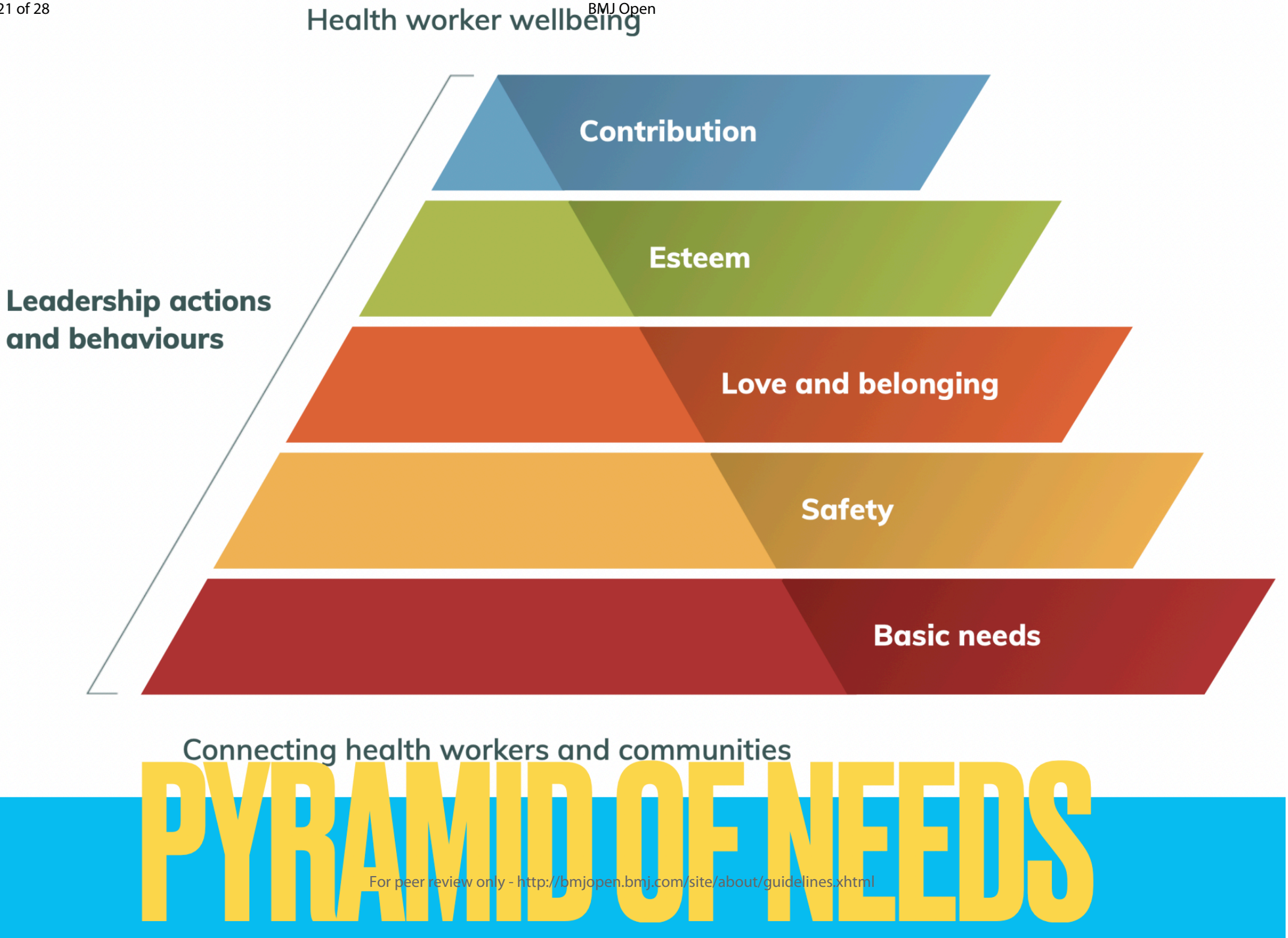
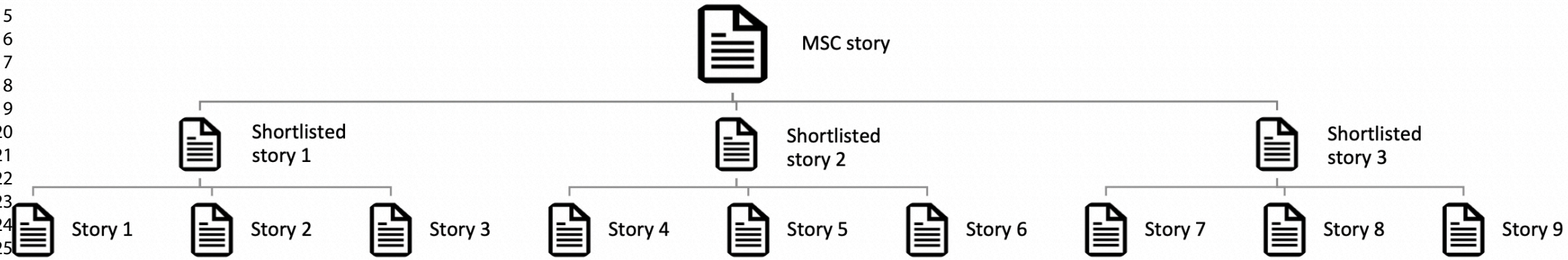
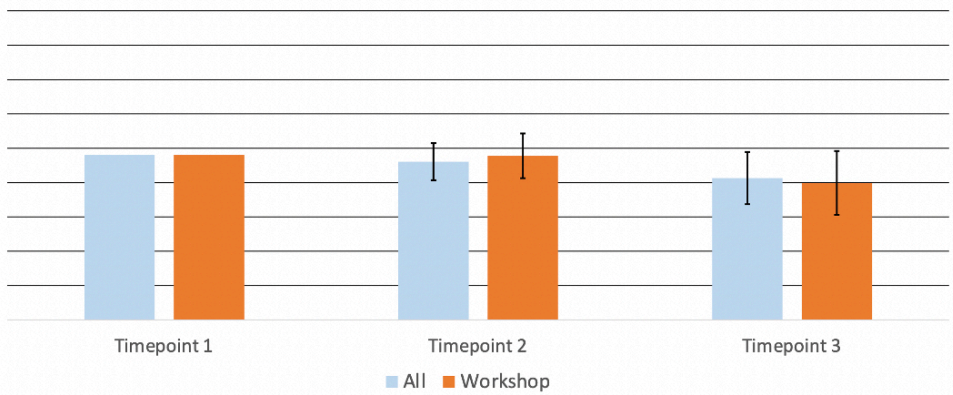
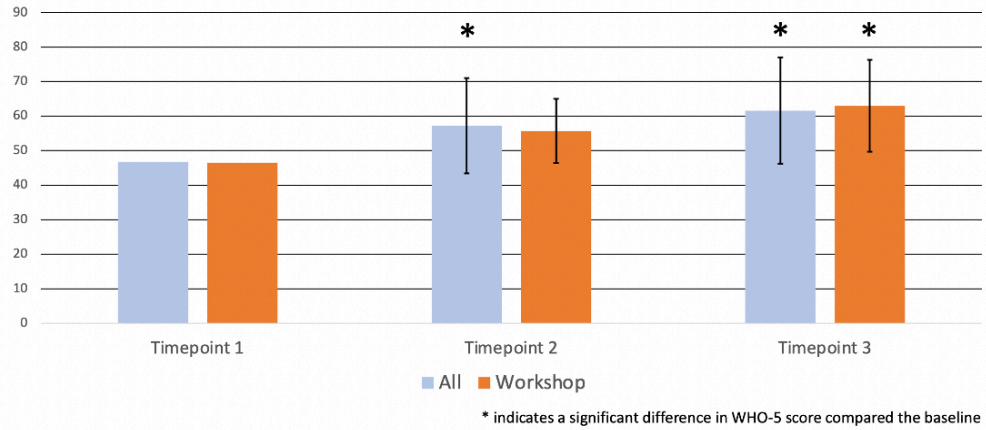


Goal 1 Getting enough rest during work hours and between shifts	• To support the existing structures to ensure work hours are safe; to foster flexibility; to role-model work-life balance; to monitor workloads and provide support for O&G DiT who are struggling
Goal 2 Eating healthy foods and engaging in physical activity	• To use environment and people-centred approaches to encourage and support O&G DiT to access healthy food options; to improve hydration in the workplace. To build opportunities to be active at work and home.
Goal 3 Being aware of where you can access mental health support at work	• To ensure the O&G DiT understands the risk to wellbeing during COVID-19, how to access additional services, and what roles they can play in helping each other stay well
Goal 4 Keeping in contact with colleagues, family and friends	• To foster a culture of care and support for the O&G DiT. To provide opportunities for connection and community
Goal 5 Advocating for management to create mentally healthy work structures	• To advocate for organisational prioritisation of wellbeing. To support the growth and development of the O&G DiT team


MSC story
Shortlisted story 1
Shortlisted story 2
Shortlisted story 3
Story 1
Story 2
Story 3
Story 4
Story 5
Story 6
Story 7
Story 8
Story 9


CBI
Timepoint 1
Timepoint 2
Timepoint 3
All
Workshop


WHO-5
90
80
70
60
50
40
30
20
10
0
*
*
*
Timepoint 1
Timepoint 2
Timepoint 3
All
Workshop
* indicates a significant difference in WHO-5 score compared the baseline

CULTURAL CHANGE

Cooperation

- Co-design
- Peer leadership
- Peer to peer learning
- Working together

Confidence

- In leadership capacity
- In teams
- In ability to look after basic needs

Communication

- Flattening of hierarchy across levels
- Giving and receiving feedback
- Normalising open communication
- Increased interactions with colleagues

Caring

- Meeting basic needs–caring for self and each other
- Link between caring for self and improved patient care

Connection

- Senior trainee doctors sharing vulnerabilities with junior trainees
- Teamwork–helping each other
- Workspace revamp–creating an organised, welcoming office space
- Knowing where to get help if needed

Appendix 1

PARTICIPANT QUESTIONNAIRE

Copenhagen Burnout Inventory & World Health Organisation Well-being Index (WHO-5)

To be collected utilising anonymised platform

CBI Part one: Personal burnout

Always, often, sometimes, seldom, never/almost never

1. How often do you feel tired?
2. How often are you physically exhausted?
3. How often are you emotionally exhausted?
4. How often do you think: "I can't take it anymore"?
5. How often do you feel worn out?
6. How often do you feel weak and susceptible to illness?

CBI Part two: Work-related burnout

To a very high degree, to a high degree, somewhat, to a low degree, to a very low degree

1. Is your work emotionally exhausting?
2. Do you feel burnt out because of your work?
3. Does your work frustrate you?
4. So you feel worn out at the end of the working day?
5. Are you exhausted in the morning at the thought of another day at work?
6. Do you feel that every working hour is tiring for you?
7. Do you have enough energy for family and friends during leisure time?

CBI Part three: Patient-related burnout

Always, often, sometimes, seldom, never/almost never

1. Do you find it hard to work with patients?
2. Do you find it frustrating to work with patients?
3. Does it drain your energy to work with patients?
4. Do you feel that you give more than you get back when you work with patients?
5. Are you tired of working with patients?
6. Do you sometimes wonder how long you will be able to continue working with patients?

WHO-5

All of the time, most of the time, more than half of the time, less than half of the time, some of the time, no time

1. I have felt cheerful and in good spirits
2. I have felt calm and relaxed
3. I have felt active and vigorous
4. I woke up feeling fresh and rested
5. My daily life has been filled with things that interest me

Appendix 2

Most Significant Change (MSC) Story Guidelines

The MSC method involves three main steps:

1. Collection of Significant Change stories from project participants.
2. Selection of Most Significant Change story, and identification of key themes.
3. Documenting and communicating the Most Significant Change stories in a report so that the program can be improved, and so others may learn about the program and its effects.

You can write or communicate your story in any way you like. The questions are provided as prompts to help frame your story; you can write as much or as little as you want for each point.

- How has COVID-19 pandemic affected your life: Personally and Professionally?

- How were you feeling before the program began?

- Which aspects of the [insert organisation] program did you make use of/experience/participate in?

- Did anything in your life change, either professionally or personally as a result of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?
    - YES/NO If your answer is NO, please tell us why you think this was the case.
    - If YES, what changed? (How are things different now?)

- Why do you think these changes happened?
    - When did the change/s happen?
    - How did the change/s to happen?

- What was the most important change for you? And Why was this change so important for you?

- Did you have any 'AHA' moments as a result of the 'Leading Kindness COVID-19 Toolkit' wellbeing program? What were they?

- Is there anything else you would like to tell us about your experience of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?

- Is there anything you would like to suggest about further development of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3 – 6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5*
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	5

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	6-7
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*7*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	7
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

The kindness COVID-19 toolkit: a mixed methods evaluation of a program designed by doctors in training for doctors in training.

Journal:	*BMJ Open*
Manuscript ID	bmjopen-2021-060575.R1
Article Type:	Original research
Date Submitted by the Author:	17-Aug-2022
Complete List of Authors:	Ward, Madeleine; Monash University, Obstetrics & Gynaecology; Monash Health, Women's & Newborn Crinall, Karen; Crinall Consulting McDonald, Rebecca; Monash Health, Women's & Newborn; Monash University, Obstetrics & Gynaecology Crinall, William; Crinall Consulting Aridas, James; Monash Health, Women's & Newborn; Hudson Institute of Medical Research, The Ritchie Centre Leung, Cheryl; Monash Health, Women's & Newborn Quittner, Danielle; Monash Health, Women's & Newborn Hodges, Ryan J; Monash Health, Women's & Newborn; Monash University, Obstetrics & Gynaecology Rolnik, Daniel ; Monash Health, Women's & Newborn; Monash University, Obstetrics and Gynaecology
Primary Subject Heading:	Obstetrics and gynaecology
Secondary Subject Heading:	Medical education and training, Qualitative research
Keywords:	COVID-19, OBSTETRICS, QUALITATIVE RESEARCH

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Authors:

Madeleine C Ward[1,2] (0000-0001-6501-7151), Karen Crinall[3], Rebecca McDonald[1,2], William Crinall[3], James Aridas[1,4], Cheryl Leung[1], Danielle Quittner[1], Ryan J Hodges[1,2], Daniel L Rolnik[1,2]

Addresses:

1. Department of Obstetrics and Gynaecology, Monash Health, Clayton, VIC, 3168, Australia
2. Monash University, Clayton, VIC, 3168, Australia
3. Crinall Consulting, VIC, Australia
4. The Ritchie Centre, Hudson Institute of Medical Research, Clayton, VIC, 3168, Australia

Corresponding author:

Dr Madeleine C Ward

Monash University

Wellington Road

Clayton, 3800, Victoria, Australia

madeleine.ward@monash.edu

The kindness COVID-19 toolkit: a mixed methods evaluation of a program designed by doctors in training for doctors in training.

Madeleine C Ward[1,2], Karen Crinall[3], Rebecca McDonald[1,2], William Crinall[3], James Aridas[1,4], Cheryl Leung[5], Danielle Quittner[6], Ryan J Hodges [2,7], Daniel L Rolnik[1,6]

1. Obstetrics and Gynaecology Registrar, Monash Health, Clayton, VIC, Australia
2. Monash University, Clayton, VIC, Australia
3. Consultant, Crinall Consulting, VIC, Australia
4. The Ritchie Centre, Hudson Institute of Medical Research, Clayton, VIC, Australia
5. Director of Training Obstetrics and Gynaecology, Monash Health, Clayton, VIC, Australia
6. Obstetrics and Gynaecology Consultant, Monash Health, Clayton, VIC, Australia
7. Program Director, Women's & Newborn, Monash Health, Clayton, VIC, Australia

Abstract

Objectives The impact of a coronavirus disease (COVID-19) specific professional development program on the wellbeing of obstetrics and gynaecology (O&G) doctors in training (DiT) working during the pandemic.

Design A mixed-method evaluation of a single group pre-post test design study.

Setting Melbourne, Australia between September 2020 and April 2021.

Participants 55 O&G DiT working across four healthcare sites of a major tertiary hospital in Victoria, Australia, were included in the program.

Interventions The delivery of a co-designed peer-to-peer (P2P) program, which identified and addressed the wellbeing goals of O&G DiT. Three interactive workshops were run alongside the implementation of a number of participant-led wellness initiatives.

Main outcome measures Repeated measures analysis of World Health Organisation Wellbeing Index (WHO-5) and Copenhagen Burnout Innovatory (CBI) scores across three time points during the program. Multilevel generalised linear mixed effects models with random intercept were fit to the data, both in the entire population ("intention-to-treat") and restricted to those who attended the workshop ("per protocol" analysis). Participatory experiences and program

learnings were captured using the Most Significant Change (MSC) technique, which included inductive thematic analysis.

Results We demonstrated an overall 31.9% improvement in wellbeing scores (p=0.006). The MSC evaluation captured a shift in workplace culture as a result of the program, with improvement across the domains of connection, caring, communication, confidence and cooperation.

Conclusions We have successfully used a mixed-methods approach to contextualise a productive program to improve the wellbeing of COVID-19 frontline healthcare workers.

Keywords Mixed methods evaluation, coronavirus disease (COVID-19) pandemic, Zoom, wellbeing program, Pandemic Kindness Movement, doctors in training, obstetrics and gynaecology, junior medical officers, healthcare worker, most significant change technique.

Article Summary

Strengths and limitation of this study
- Utilises a mixed-method evaluation, enhancing the interpretation of outcomes and adding valuable information about the impact, acceptability and utility of the intervention. - Provides a detailed description of the peer-led and peer-to-peer participatory processes used to affect a co-design approach to program development. - Use of the Most Significant Change methodology, a powerful qualitative evaluation tool which provokes broad reflections in participants and provides an avenue for organisational leadership to initiate improvements and build capacity. - Limitations included sample size and generalisability; with a need to further validate the program via larger studies with the inclusion of other populations.

Introduction

The novel coronavirus disease (COVID-19) pandemic has had an unparalleled impact on the provision of healthcare, resulting in significant physical and emotional burden on those accessing and servicing the acute hospital setting.[1,2] It has created further pressure on an already vulnerable group of doctors with additional risks from exposure to an infectious disease, reduced resources and high workload.[1,3]

Burnout is a recognised occupational hazard for healthcare workers and encompasses emotional exhaustion, withdrawal from patients and loss of job satisfaction.[4] Ensuring the health of workers is vital for the delivery of high quality service, with healthy workers

demonstrated to provide better customer relations, have more positive attitudes, and be more enthusiastic.[3,5] In comparison to other professionals, doctors are ten times more likely to suffer from psychological distress, especially those under the age of thirty.[6,7] These findings are not isolated to the Australian medical workforce, with 69% of USA healthcare workers reporting workplace stress and 37% of UK doctors requiring additional care due to burnout.[4] More than a decade ago a national report highlighted the significant distress of Australian doctors in training (DiT) with less than 30% satisfied with their career, over half (54%) losing compassion for patients and more than two thirds (69%) experiencing burnout.[8] Obstetrics and Gynaecology (O&G) DiT work long hours and shift work, which are known to contribute to dissatisfaction and reduced wellbeing, as well as occupational stress, burnout and mental health issues.[3]

Despite safety and quality healthcare indicators being drivers for accountability there is a failure to recognise the need to support the wellbeing of healthcare workers.[7] In recognition of the immediate risk to the wellbeing of the Women's Health DiT group and associated impacts on health service provision we aimed to provide an appropriately resourced, efficient and effective COVID-19 pandemic-specific professional development program focused on improving the wellbeing of O&G DiT. A program, aimed at informing the future development and implementation of similarly focussed wellbeing initiative was co-designed by the O&G DiT group and delivered via a peer-to-peer (P2P) teaching model. The aims were to:

1. Assess the wellbeing and symptoms of burnout among the Monash Women's DiT in O&G.
2. Provide immediate and practical tools and strategies to enhance the wellbeing of Monash Women's DiT working during the COVID-19 pandemic.
3. Generate an evidence base, informed by qualitative and quantitative data, to advise future implementation.

Monash Women's, a major tertiary hospital in Victoria, Australia has been a leader in the implementation of COVID-19 strategic management plans, policies and procedures with the safety and wellbeing of staff, patients and the community at the forefront.[9]

The aim, specific to the mixed methods analysis, was to evaluate and explore the impact of the covid-19 specific wellbeing program, as a whole, on the cohort of O&G DiT.

Methods

Here we list the steps involved in the P2P program development, including the details of the co-design processes followed. The integration of a mixed-methods analysis is described, an approach which takes advantage of the considerable impact qualitative research methods can have on reviewing health interventions.[10] A quantitative evaluation was conducted of the World Health Organisation Wellbeing Index (WHO-5) and Copenhagen Burnout Innovatory (CBI) measures that were administered prior to and at multiple time points following the program.[11,12] Qualitative analysis utilising the Most Significant Change (MSC) technique, is also described and the key outcomes listed.

Patient and public involvement

All 55 Monash Women's doctors in training (DiT) working across four sites – one tertiary and three secondary hospitals (Monash Medical Centre, Dandenong District Hospital, Moorabbin Health and Casey Hospital) were invited to participate in the study. Our study utilised a convenience sample size without a formal power calculation. Recruitment was maximised via advertising utilising group email. An introduction and orientation session was held with opportunity to complete recruitment at this time, and reminder emails were sent to increase uptake. Recruitment at the beginning of the first workshop also took place. Inclusion criteria included being a current O&G DiT who were both available and willing to attend the workshops and complete the questionnaires.

The intervention

An overarching self-selected group of senior DiT, known as 'champions', initiated the project, formulated broad goals (Figure 1) and directed activities in line with those promoted by Beyond Blue 'Protecting your mental health and wellbeing as a healthcare worker'.[13(15)] Monash Women's executive leaders were also engaged to participate and act on organisational level solutions. A co-design process and peer to peer learning model were identified as essential to effective development and implementation of the proposed program. A multi-format toolkit was developed, incorporating workshops, activities, and resources.

Seven online workshops, each of one-hour duration, were delivered by DiT to their peers during protected teaching time on 17 September 2020, 24 September 2020 and 5 November 2020. This model was selected to maximise positive impacts and enable rapid implementation of change.[14(13)] It is also a familiar style of learning given its similarity to the traditional 'journal club' style of medical education frequently used in the training of Australian medical doctors.

Workshop topics were modelled on the 'Pyramid of needs', for health worker wellbeing (Figure 2), (based on Maslow's hierarchy of needs),[15(14)] and covered six topic areas: basic needs, safety, love and belonging, esteem, contribution and leadership. The seventh workshop was devoted to reviewing topics presented. Workshop content dissemination was maximised with recordings, webmail links and online communities. In keeping with the co-design approach, brainstorming sessions were included, and ideas generated were disseminated to the O&G DiT cohort via email and posters. P articipant-led initiatives were also encouraged and developed during the workshops, and advocating for personal solutions was supported.

The first workshop addressed meeting basic needs and was led by a more senior DiT. The session provided space for participants to acknowledge the importance of hydration, nutrition, shelter and sleep. Facilitated break out groups worked together to share how they were being impacted by the COVID-19 pandemic and ideas on how improvements at both an individual and organisational level could be achieved. These ideas were central to informing the larger goals and actions of the program, including the development of the policy on dealing with doctors in distress.

Activities involved the provision of a drink 'hydration' station to encourage breaks, improvements to the doctor office space and social online sessions by Zoom Cloud Meetings (Zoom Video Communications, San Jose, CA, USA).

Resources included the creation and display of posters articulating the main workshop points and a team social media app. Further information on the program, including a workbook and templates can be found in resources: 'Monash Women's Leading Kindness COVID-19 Toolkit Pilot Project Most Significant Change Evaluation Report';[16] 'Monash Women's Leading Kindness COVID-19 Toolkit Pilot Project Quantitative Evaluation Report', and 'Start up: A Kindness COVID-19 Toolkit'.[17,18]

The evaluation strategy

Quantitative analysis

The CBI and WHO-5 questionnaires, both well-validated and standardised, were employed to evaluate the pre-existing wellbeing and symptoms of burnout in the cohort O&G DiT (September 2020, timepoint one).[12,15] Both were repeated at timepoint two (November 2020) and at timepoint three, six months following the completion of the workshop (April 2021). Questionnaires were delivered and secured electronically via the online data collection tool, Qualtrics (Qualtrics, Provo, UT, USA), with surveys labelled with an anonymous but memorable code, created by the participant, to preserve confidentiality.

The WHO-5 is a standardised questionnaire, which asks five questions focused on wellbeing in the preceding two-week time period (Appendix 1). A total score of less than 50 is considered to represent reduced wellbeing.[11] The CBI assesses the load of personal, work and patient related factors on burnout, with its benefits being a readily available and brief evaluation tool. A score of 25-50 indicates an intermediate level of burnout, and greater than 50 a high level of burnout.[19]

Statistical analyses were performed in Stata 16.1.(StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LLC). To compare the CBI and WHO-5 scores after exposure to the program (timepoints two and three) with those before its implementation (timepoint one) accounting for the repeated measures design, multilevel generalised linear mixed effects models with random intercept were fit to the data, both in the entire population ("intention-to-treat") and restricted to those who attended the workshops ("per protocol" analysis). In these models, the measurements timepoints were treated as fixed effects and participants were treated as random effects. The assumptions of linear additivity and homogeneity of the residuals were assessed by inspection of residual versus fitted plots. Effect estimates are reported as the mean difference with 95% confidence intervals, and p-values below 0.05 were considered statistically significant.

Qualitative analysis

Qualitative evaluation utilising the MSC technique was chosen to gain insight into participants' experience of the personal and professional impacts of the toolkit. Story gathering interviews took place via Zoom sessions between 8 December 2020 and 4 January 2021. (Appendix 2) Nine stories of change were collected from interviews that lasted between 20 and 40 minutes. To ensure rigour and impartiality external expertise in qualitative analysis was engaged. MSC was chosen because it seeks to learn about participants' perceptions of program impacts by evaluating their stories of significant change, and thereby complemented the program's participatory principles: co-design, peer leadership and P2P learning. MSC was also selected because of its focus on 'what works well and how to do more of what works'.[20]

Consistent with the MSC technique, the evaluation incorporated three main steps:

1. Collection of Significant Change stories via interviews.
2. Selection of the Most Significant Change story by a stakeholder panel, and identification of key themes through manual inductive analysis of MSC stories and selection panel discussion.
3. Documenting and communication of the Most Significant Change story and key themes.

The MSC technique involves a hierarchical selection process which narrows the data down to one story representing the most significant change. A stakeholder panel consisting of trainees and supervisors, as well as interview participants who were contributors of stories of change, undertook a two-tiered process culminating in the selection of one significant story from a total of nine stories (Figure 3). Prior to the selection panel the nine stories were randomly divided into three groups of three. Stories from each group were then read aloud in the panel session and were shortlisted via an open voting process. Individual reasons for selection were shared and recorded through open discussion and agreement was reached on one most significant change story.

To gain a comprehensive picture of the range of significant changes experienced by participants a manual inductive analysis of all nine stories and the transcript of the selection panel session discussion was conducted to capture emergent themes. This methodology is discussed in detail in other publications.[16,21,22]

Results

Program overview

The program, which was evaluated as a whole rather than the individual components, included; seven one hour live remote workshops (covering each of the six themes and one review session); circulated recordings of the workshops; three online social sessions; a hydration station stocked with drinks for each work site; six laminated wall posters with the main concepts from the workshops posted at each work site; a senior trainee education session on supporting junior trainees; a meeting with senior management advocating for wellbeing initiatives; a business proposal for a wellbeing officers; renovation of the doctor's office spaces and the development of a social media app.

Participants

Forty-six (83.6%) DiT completed the initial WHO-5 and CBI at timepoint one. Seventeen DiTs, including residents and registrars, attended at least one of the live workshops, the recorded workshops were circulated to all 55 DiT however it is not known how many viewed them in their own time. All 55 DiT were exposed to the initiatives of the program, however specific details of their uptake are unknown. Following the completion of the workshops (timepoint two), 27 responses were collected, of which 59.3% (n=16) were workshop participants (live or recorded viewing). At timepoint three 11 responses were collected, with 63.6% (n=7) being participants of the workshops.

Quantitative analysis: CBI and WHO-5

Copenhagen Burnout Inventory (Figure 4)

Among all DiT (those who participated in the workshop and those who did not), there was a mean reduction of 2.0 points (95% CI: -7.4 to 3.3) at timepoint two compared to timepoint one, although this reduction was not statistically significant (p = 0.454). There was a mean reduction of 6.8 points (95% CI: -14.4 to 0.7) at timepoint three compared to timepoint one, demonstrating a trend towards statistical significance (p = 0.077). Similarly, among those who participated in the workshop, there was a mean reduction of 0.3 points (95% CI: -6.8 to 6.2) at timepoint two compared to timepoint one, although this reduction was not statistically significant (p = 0.935). There was a trend towards statistical significance (p = 0.086) at timepoint three compared to timepoint one with a mean reduction of 8.2 points (95% CI range: -17.5 to 6.2).

WHO wellbeing index (Figure 4)

Among all participants there was a statistically significant mean increase of 10.5 points (95% CI: 3.3-17.7, p=0.006) at timepoint two compared to timepoint one, and a statistically significant mean increase of 14.9 points (95% CI range: 0.5-29.3, p=0.006) at timepoint three compared to timepoint one. Analysis restricted to those who participated in the workshop showed a mean increase of 9.2 points that trended towards statistical significance (95% CI: -0.2 to 18.5, p = 0.054) at timepoint two compared to timepoint one, and a significantly higher WHO score at timepoint three, with a mean increase of 16.4 points (95% CI range: 3.2 to 29.7, p = 0.015) at timepoint three compared to timepoint one.

Qualitative Analysis

The complete methodology and outcomes of the qualitative analysis have been published elsewhere, below we list a summary of the findings.[16,17]

The MSC story

The selected story 'Team cohesiveness' (Appendix 3) was contributed by a junior O&G DiT workshop participant. It was chosen by the panel because it described how the COVID-19 toolkit brought about cultural change and fostered a sense of kinship by enabling basic needs to be met, "break[ing] down hierarchical barriers within the Monash Women's Health team" and building team cohesiveness multi-directionally.

> *"With the introduction of the Wellbeing program there was a more organised sense of looking out for each other… A highlight was senior clinicians telling their own stories…Witnessing their fears and concerns, and their approaches to challenges makes you more impressed by their achievement, you feel like challenges are more approachable, the steps ahead are more attainable...The program was also an opportunity to address the things that make a cohesive team, that make us all better together."*

Themes

Significant changes linked to five interconnected themes (Figure 5) were woven throughout the nine stories and encapsulated in the most significant change story selected by the panel.

Connection: Connections between DiT were strengthened through the P2P learning model of the workshop design, with one participant reflecting that "hearing others talk about their experiences and feelings of not being okay and sharing my experiences and feelings…made me feel more connected and less alone". Another participant observed: "One of the most important things to come out of the program during the pandemic was being closer to colleagues that I don't work with every day".

A participant story described a significant change for them as "a noticeable physical difference…the revamp of our doctors' office, there is new furniture, and plants in there now, it is fresh and more open. We feel welcome; now I've somewhere that I belong at work".

Communication played an important role in fortifying connections. The impact of the workshop session which explored 'Esteem' was recalled as motivating DiT to connect with one another by engaging in two-way feedback. An example of how this was enacted was explained by one participant as paying attention to asking others "about their shift, and how they felt they went, and…ask[ing] them for feedback on how they thought I had gone".

Caring: Caring emerged as a significant change. Participants recognised "a more organised sense of looking out for each other". The workshop on meeting basic needs, in particular, shifted how DiT thought about self-care, as well as encouraging greater care for each other. Participants explained that "people were asking, 'Have you had water this morning? Have you had enough to eat?'". They also reflected "the program reminded us to take care of ourselves, and to support each other, even on long shifts when we are very stressed at work".
Another observed: "Overall, the general culture at work has changed, everyone is more mindful of each other's wellbeing."

Communication: The program offered alternative ways to share information and opened up communication vertically and horizontally. Investing in the revamping of the doctor's office space was experienced as a powerful gesture by participants. The program was described as having created a "space to talk" allowing trainee doctors to "hear each other".

Another participant explained, "The workshop on giving feedback; asking for feedback and how to give feedback in a constructive, rather than critical way, I took that on. I will definitely remember that in the future. The workshop normalised open conversation". Others observed

an increase in interactions with colleagues, More open communication facilitated supporting each other, "When I spoke about what I was going through, others then asked me for a coffee or a meal and shared their version of not being okay."

Confidence: All participants felt more confident as a result of experiencing the program. They were not only more confident about asking for help, they also felt empowered to be leaders and bring about change.

One DiT reflected that they had "learnt that courage is not the absence of fear – it is the ability to act in the presence of fear". Another explained that for them the "most important change brought about by the wellbeing program…was recognising my agency. I learned there were changes I could make." The peer-to-peer delivery was highlighted as a major contributor to program impact, with one participant observing "a highlight was senior clinicians telling their own stories. You can have grandiose ideas about others at work, especially the seniors you admire, how they know everything and do everything right. Witnessing their fears and concerns, and their approaches to challenges makes you more impressed by their achievement, you feel like challenges are more approachable, the steps ahead are more attainable".

Cooperation: The program aimed to bring O&G DiT together; to reflect, learn and grow skills to improve wellbeing, and most importantly to have their concerns acknowledged and acted upon at an organisational level. Participants of the program observed a shift to more cooperative workplace practices, reporting that "the program was also an opportunity to address the things that make a cohesive team, that make us all better together. More than before the whole team stepped up to help each other make it through the day together*."*

Discussion

'The difference that made a difference.' [22]

This study evaluated an educational program to improve wellbeing designed by and for a group of 55 O&G DiT at a major tertiary hospital in Victoria, Australia during the 2020 COVID-19 pandemic. We tracked the indicators of wellbeing and burnout with collection of surveys before (n=46 and after (n=27 and 11) the implementation of seven workshops, which were one component of a collection of initiatives that comprised a toolkit of resources. Nine workshop participants were interviewed about their most significant experiences of change resulting from

the program. We demonstrated an overall 31.9% improvement in wellbeing scores. The qualitative evaluation identified the most significant change, ie. 'the difference that made a difference' as an overall positive shift in workplace culture associated with change across five domains: connection, caring, communication, confidence and cooperation.

The impact of COVID-19 on the safety and wellbeing of healthcare workers is well documented.[2,23,24,25] Ellis et al.[2] reported an increase in surgical error due to the combined effects of COVID-19 on doctors' sleep hygiene, concerns regarding infection exposure and the burden of personal protective equipment restricting movement and communication. However, despite well-known risks to DiT and an urgent call for interventions,[6,26] there has been a lack of validated programs aimed at improving their wellbeing.[7,27]

During the third month of the second Victorian COVID-19 pandemic lockdown, which lasted 112 days from the 6th of July 2020 to the 26th of October 2020,[28] we observed that Monash Women's DiT were experiencing significantly reduced wellbeing (mean score 46.7) and intermediate levels of burnout (mean score 48.1). Participants in the qualitative evaluation described finding themselves overwhelmed. For some, the pandemic exposed vulnerabilities more so than ever before. One participant shared that "the COVID-19 pandemic affected [their] life – personally and professionally – in every way." In the workplace trainees reflected that there was "a lot of fear across staff, patients, administrators; everyone." They shared their experiences of being both "extremely grateful to have work and…at the same time…a level of resentment about having to go to work, and being expected to see people and just absorb the daily changes in PPE protocols, wearing visors, face masks and glasses, at times feeling claustrophobic; like you couldn't escape, not being able to eat or drink during a busy shift."

DiT working in O&G are responsible for providing care across a range of clinical areas within the health service site, including the emergency department, outpatient clinics, inpatient wards, operating theatres, and birthing suites. In a recent survey obstetricians and gynaecologists were amongst the highest at risk of physician burnout.[29] Anticipating that the added workload generated by a pandemic situation would pose additional risk to the wellbeing of O&G DiT is not unwarranted, with Ochsmann et al.[30] identifying strain levels as directly related to overtime worked. The provision of safe care also depends on effective communication with patients, their families and across multidisciplinary teams spanning all levels of the

organisational structure. These multi-dimensional care and communication challenges have also been demonstrated to increase risk for emotional and physical fatigue.[31]

The *'Monash Women's COVID-19 leading kindness toolkit'* program demonstrated a 31.9% improvement in the wellbeing index for all DiT participants, and contributed to safeguarding against worsening burnout symptoms. Those who attended a component of the integrated workshops experienced slightly greater impact (35.5%) on wellbeing over time. The overall achievement of the project, as expressed by participants in their stories of change, was a shift to a more caring and supportive workplace culture. Junior and senior DiT felt more connected as colleagues and were more confident about advocating for change and communicating with one another about their work. The impact of workplace friendships has been shown to be inversely related to workplace stress with healthcare workers relying most heavily on strong peer-support, sharing with senior staff and supportive social networks when facing a crisis.[3] The P2P style of our program was highlighted as a strength by participants. This is consistent with the finding of Chanchlani et al.[6] who evaluated a P2P mentoring program and demonstrated an improved sense of community and support. Similarly, Walton et al.[9] identified the important role of P2P interactions in the acquisition of complex non-technical skills.

Based on our experience in this initiative, we strongly advocate for a mixed-methods approach in the evaluation of health care programs. Triangulating qualitative and quantitative methods enhances interpretation of outcomes, and provides valuable information about the impact, acceptability and utility of interventions.[12,31] This integrative approach utilises the complementary capacities of quantitative research in defining measurable variables and qualitative research in investigating complex social constructs.[12] Exploring reasons for participant satisfaction or dissatisfaction, lack of adherence and causes of conflicting outcomes in different population groups are examples of the way qualitative analysis can enhance quantitative findings.[32] Despite growing recognition of the value of mixed-method designs there remains a lack of published medical studies employing a dual-analysis approach.[12] This is s upported by Lewin et al.[31] who conducted a review of the Cochrane register and identified just one third undertook a combined quantitative and qualitative analysis. Recognised barriers to mixed-method designs in medical research include the need for adequate resourcing, the time-consuming nature of the research process and difficulty accessing appropriately experienced qualitative researchers.[31]

Implications and limitations

The program was enthusiastically welcomed, and our findings attest to the benefits received by participants. The triangulation of quantitative and qualitative results demonstrates DiT were provided with tools to address burnout and improve wellbeing. Although our results suggest an improvement in burnout over time, this effect did not reach significance. Given the small numbers, our study may have been underpowered to detect a significant improvement in burnout. Alternatively, the program may have limited impact on improving burnout. However, given the entire cohort remained within the intermediate burnout category (score 25-50), our findings support the program's success in protecting against worsening burnout during the pandemic.

The results of this study are limited by the small sample size . Participation in the workshop component of the program was only 30.9% (n=17), despite the workshops being delivered during dedicated teaching time. This highlights the demands being placed on trainee doctors over this time and reflects the practice of clinical responsibilities taking priority over educational opportunities. The P2P and co-designed structuring of the program as a 'toolkit' enabled the workshop content and initiatives to reach the non-attending DiT, affecting a rapid execution of changes and success of the program.

We also self-imposed limitations on the collection of participant characteristics in order to preserve anonymity. A key component of the MSC technique is sharing personal stories. This presents challenges for maintaining confidentiality. The sample size and close working relationships meant maintaining anonymity could not be guaranteed. We addressed this by disaggregating stories, and by ensuring participants were informed that they may be identified.

Given the collection of data was dependent on the voluntary completion of interviews and surveys our analysis is subject to non-response bias. Raising the possibility that those who responded were more motivated and healthier, and people with more burnout or depression did not respond. Our small numbers limited the ability to undertake inverse probability weighting or multiple imputation to address this. The mixed-methods design strengthened the findings of the evaluation, providing insight and breadth to inform future implementations.

Over the last few years, there has been a greater focus on the nurturing of emotional intelligence. Many of these efforts have involved self-directed learning, action coaching and formalised mentoring programs.[33] These attempts have faced substantial system-based obstacles and have, at times, paradoxically penalised the individual doctor for failing to self-care. Doctors in training are a highly goal motivated group, yet messages that a lack of resilience, weakness, and laziness typify those who succumb to these stressors is enduring.[3,7,33] The harm from erroneous messages sent through labelling doctors as super-humans is also well documented; often as a gesture of thanks this culture lends itself to messages of the need to 'tough it out'.[34] Together, these run the risk of adding to the misconception that seeking help is a sign of weakness, failure and not having what it takes to survive the rigors of medical training.

In co-designing our program, we were able to create a system of resources, which were meaningful and useful. In combination with a solid commitment from the organisation to support and see through the delivery of the program, we effectively created a cultural shift and built capacity with a lasting impact for our team. The provision of programs with a directive to protect and prevent healthcare workers from burnout is desperately needed. Interventions must be directed and targeted, recognising time constraints, transient working locations and competing demands. Additionally, their evaluation is imperative.[7] It is vital that doctors feel safe to seek help, and more importantly administrators need to identify, track and monitor the wellbeing of employees and act well before crisis point is reached [35].

We have successfully used a mixed-methods approach to contextualise a productive program to improve the wellbeing of COVID-19 frontline healthcare workers. We hope the evidence generated from our program contributes to informing the implementation of future programs within other healthcare groups and settings.

Figures

Figure 1: Goals of the 'Monash Women's leading kindness COVID-19 toolkit'

Figure 2: Pyramid of Needs

Figure 3: MSC selection process

Figure 4: Repeated measures CBI and WHO-5 scores for all and restricted to those who participated in the 'Monash Women's leading kindness COVID-19 toolkit' workshops

Figure 5: Themes revealed by stories which came together to shift the workplace culture

Appendices

Appendix 1: Participant Questionnaire

Appendix 2: Most Significant Change (MSC) Story Guidelines

Appendix 3: Participant Stories of 'Most Significant Change'

a. Contributorship

MW, RM, JA and DR contributed to the study design and implementation. Quantitative data was collected by JA, RM and MW, and analysed by DR, RM and MW. Qualitative data collection and analysis was conducted by KC and WC. MW oversaw the compilation of the first draft of the manuscript. CL and DQ contributed to the program design and development. RH acted as a senior supervisor and led program resources allocation. All listed authors contributed to the manuscript and meet authorship criteria, without the exclusion of others.

b. Funding Statement

The *'Monash Women's leading kindness COVID-19 toolkit'* wellbeing program and its evaluation was funded by Monash Health Foundation grant (no award/grant number). The program and analysis were undertaken independently and without influence from the funding body.

c. Competing of Interests

"All authors have completed the Unified Competing Interest form (available on request from the corresponding author) and declare: support from Monash Health Foundation COVID-19 Research grant for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, no other relationships or activities that could appear to have influenced the submitted work." (BMJ Author Guidelines, 2021)

d. Ethics approval

The project was funded by the Monash Health Foundation and granted ethics approval from Monash Health Human Research Ethics Committee (QA/68545/MonH-2020-230841(v2)). Within the manuscript all details of the study are accurately and transparently provided in an honest account of the study.

e. Data sharing

We commit to undertaking all reasonable requests to share relevant data. De-identified raw data is securely stored within Qualtrics and with the research team. Open access evaluation reports are available at: https://leadingkindnesscovid19toolkit.wordpress.com/

Acknowledgments

The Pandemic Kindness Movement was a vital resource for inspiration and implementation of the program. We would like to thank the A/Prof Jane Munro along with all the clinicians and experts who contributed and curated this wonderful collection of information in such a user friendly and available format.

We would like to acknowledge the overarching guidance provided by A/Prof Jacqueline Boyle and A/Prof Arunaz Kumar who were instrumental in the planning of the project and evaluation processes.

We would also like to extend our gratitude to Prof Beverly Vollenhoven, Dr Mark Tarrant, Dr Risha Bhatia and A/Prof Arunaz whose participation and feedback were crucial to the success of the evaluation.

We would also like to thank the Monash Women's O&G DiT who co-designed this pilot project along-side us. Especially to those who took the time to participate, present and provided vital feedback during a time in which they were most under the pump. Without your efforts there would be no program to report on.

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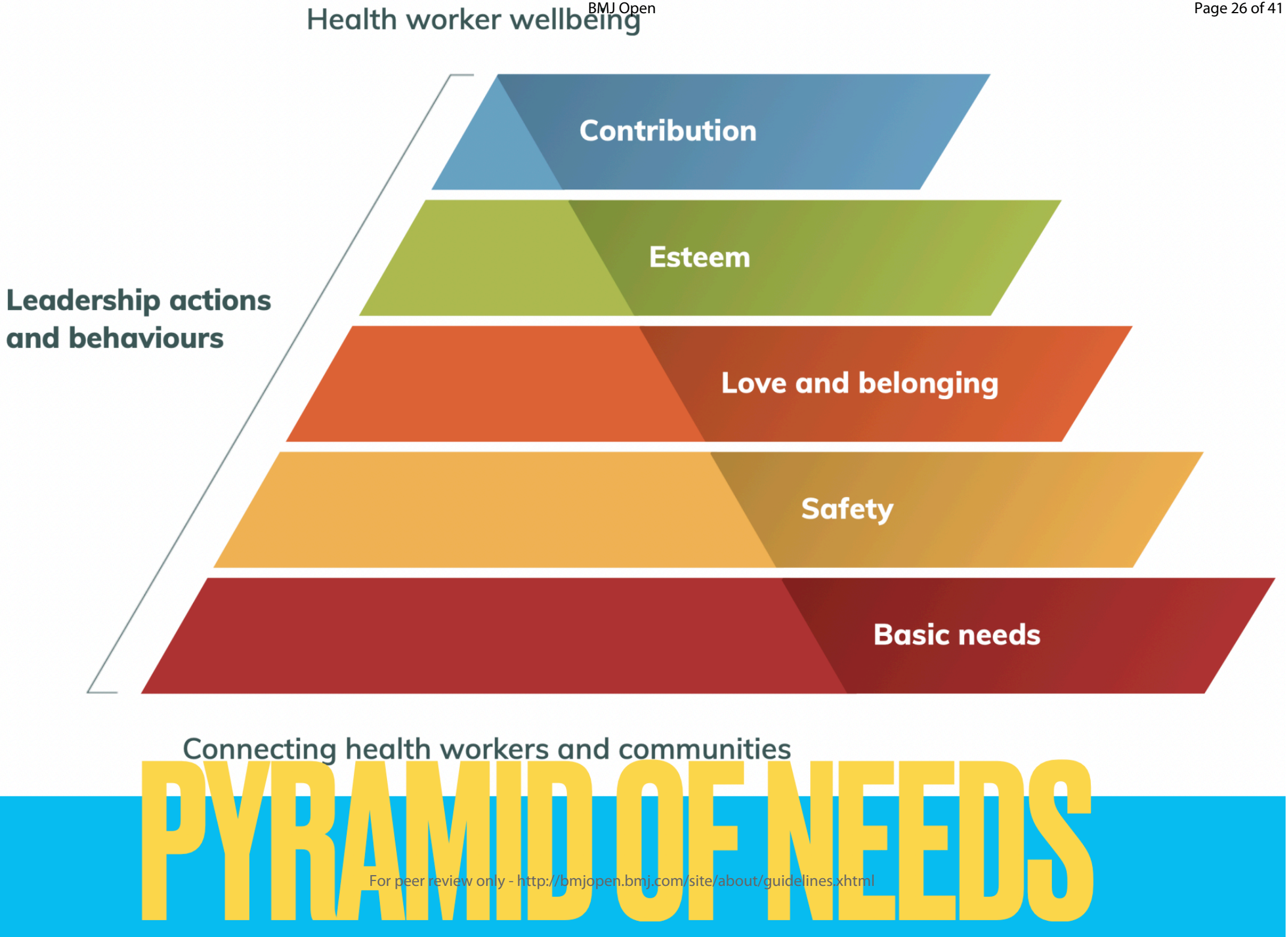
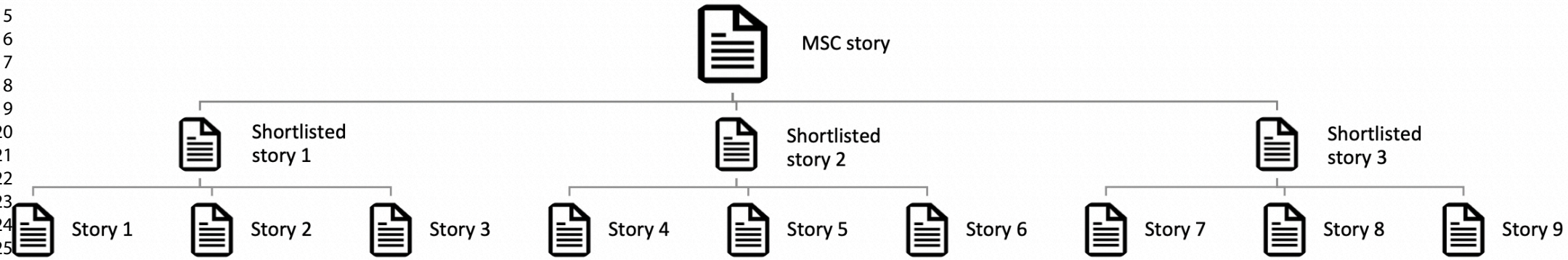
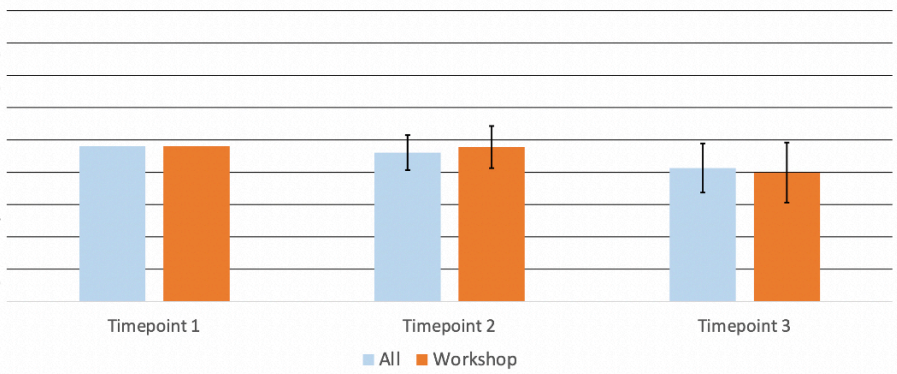
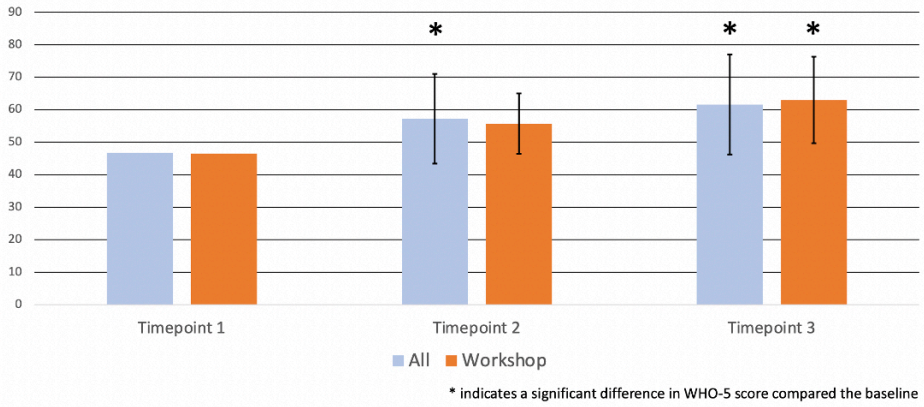
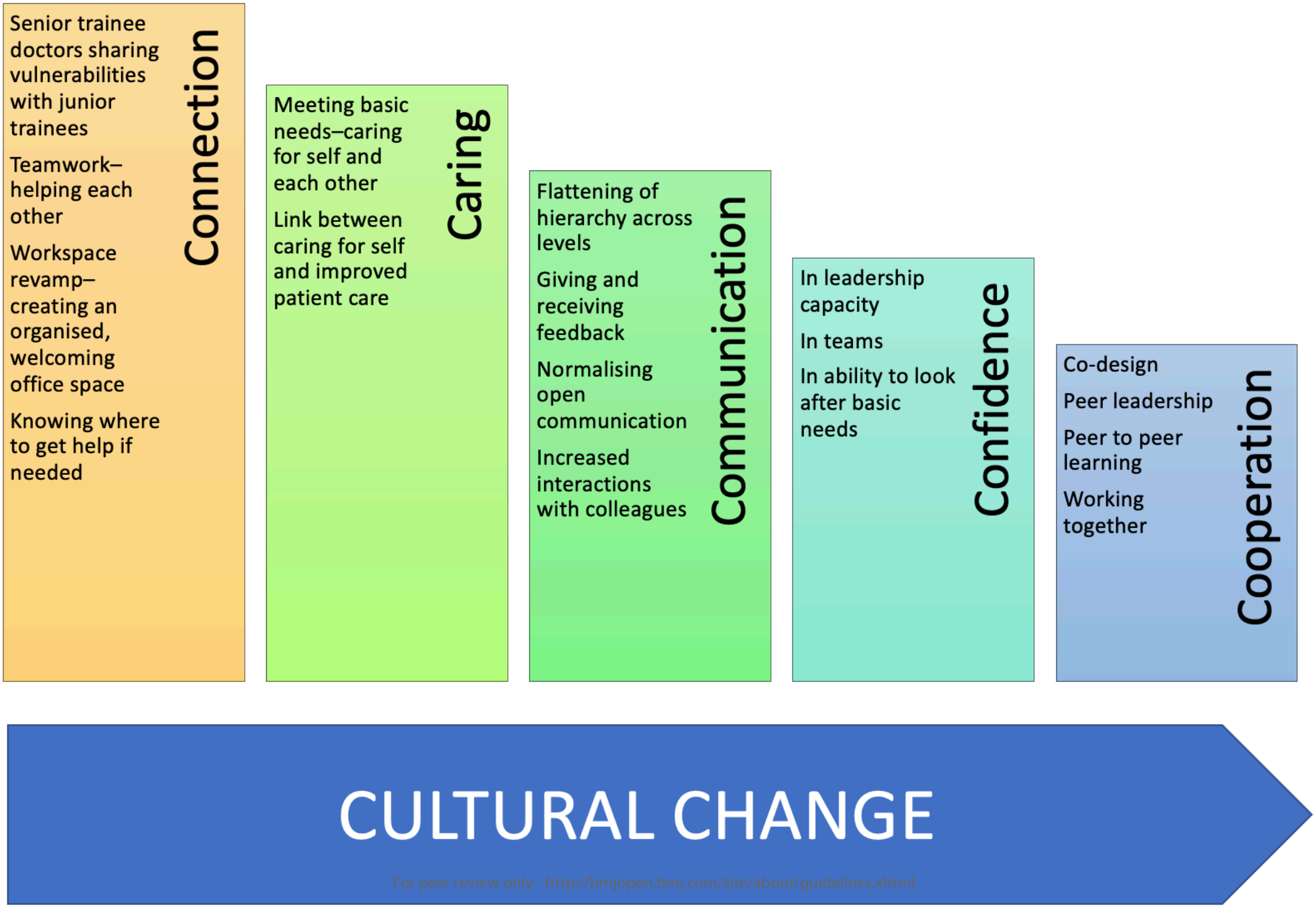
Goal 1 Getting enough rest during work hours and between shifts	• To support the existing structures to ensure work hours are safe; to foster flexibility; to role-model work-life balance; to monitor workloads and provide support for O&G DiT who are struggling
Goal 2 Eating healthy foods and engaging in physical activity	• To use environment and people-centred approaches to encourage and support O&G DiT to access healthy food options; to improve hydration in the workplace. To build opportunities to be active at work and home.
Goal 3 Being aware of where you can access mental health support at work	• To ensure the O&G DiT understands the risk to wellbeing during COVID-19, how to access additional services, and what roles they can play in helping each other stay well
Goal 4 Keeping in contact with colleagues, family and friends	• To foster a culture of care and support for the O&G DiT. To provide opportunities for connection and community
Goal 5 Advocating for management to create mentally healthy work structures	• To advocate for organisational prioritisation of wellbeing. To support the growth and development of the O&G DiT team




MSC story
Shortlisted story 1
Shortlisted story 2
Shortlisted story 3
Story 1
Story 2
Story 3
Story 4
Story 5
Story 6
Story 7
Story 8
Story 9


CBI
Timepoint 1
Timepoint 2
Timepoint 3
All
Workshop


WHO-5
90
80
70
60
50
40
30
20
10
0
*
*
*
Timepoint 1
Timepoint 2
Timepoint 3
All
Workshop
* indicates a significant difference in WHO-5 score compared the baseline



Appendix 1

PARTICIPANT QUESTIONNAIRE

Copenhagen Burnout Inventory & World Health Organisation Well-being Index (WHO-5)

CBI Part one: Personal burnout

Always, often, sometimes, seldom, never/almost never

1. How often do you feel tired?
2. How often are you physically exhausted?
3. How often are you emotionally exhausted?
4. How often do you think: “I can’t take it anymore”?
5. How often do you feel worn out?
6. How often do you feel weak and susceptible to illness?

CBI Part two: Work-related burnout

To a very high degree, to a high degree, somewhat, to a low degree, to a very low degree

1. Is your work emotionally exhausting?
2. Do you feel burnt out because of your work?
3. Does your work frustrate you?
4. So you feel worn out at the end of the working day?
5. Are you exhausted in the morning at the thought of another day at work?
6. Do you feel that every working hour is tiring for you?
7. Do you have enough energy for family and friends during leisure time?

CBI Part three: Patient-related burnout

Always, often, sometimes, seldom, never/almost never

1. Do you find it hard to work with patients?
2. Do you find it frustrating to work with patients?
3. Does it drain your energy to work with patients?
4. Do you feel that you give more than you get back when you work with patients?
5. Are you tired of working with patients?
6. Do you sometimes wonder how long you will be able to continue working with patients?

WHO-5

All of the time, most of the time, more than half of the time, less than half of the time, some of the time, no time

1. I have felt cheerful and in good spirits
2. I have felt calm and relaxed
3. I have felt active and vigorous
4. I woke up feeling fresh and rested
5. My daily life has been filled with things that interest me

Appendix 2

Most Significant Change (MSC) Story Guidelines

The MSC method involves three main steps:

1. Collection of Significant Change stories from project participants.
2. Selection of Most Significant Change story, and identification of key themes.
3. Documenting and communicating the Most Significant Change stories in a report so that the program can be improved, and so others may learn about the program and its effects.

You can write or communicate your story in any way you like. The questions are provided as prompts to help frame your story; you can write as much or as little as you want for each point.

- How has COVID-19 pandemic affected your life: Personally and Professionally?

- How were you feeling before the program began?

- Which aspects of the [insert organisation] program did you make use of/experience/participate in?

- Did anything in your life change, either professionally or personally as a result of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?
    - YES/NO If your answer is NO, please tell us why you think this was the case.
    - If YES, what changed? (How are things different now?)

- Why do you think these changes happened?
    - When did the change/s happen?
    - How did the change/s to happen?

- What was the most important change for you? And Why was this change so important for you?

- Did you have any 'AHA' moments as a result of the 'Leading Kindness COVID-19 Toolkit' wellbeing program? What were they?

- Is there anything else you would like to tell us about your experience of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?

- Is there anything you would like to suggest about further development of the 'Leading Kindness COVID-19 Toolkit' wellbeing program?

Appendix 3

PARTICIPANT STORIES OF 'MOST SIGNIFICANT CHANGE'

As published in 'Crinall, K and Crinall, W (2021), *Monash Women's Leading Kindness COVID-19 Toolkit Pilot Project Most Significant Change Technique Evaluation Report*, Crinall Consulting, Melbourne, Australia.'
Available at: https://leadingkindnesscovid19toolkit.wordpress.com/

Team cohesiveness*

With the introduction of the Wellbeing program there was a more organized sense of looking out for each other. I really liked the basic needs workshop, which highlighted the simple things everyone needs to attend to–that you can help other people attend to–which are not always our first priority, like eating, drinking water and getting enough sleep. After the workshop people were asking "Have you had water this morning? Have you had something to eat?" There was recognition that it was not weak or lazy to take a break to drink and eat, you have to do it to function. Everyone went to medical school, it's not like we don't know that.

The other thing that I liked about the program, and in the aftermath, was how it seemed to break down hierarchical barriers within the Monash Women's Health team. A highlight was senior clinicians telling their own stories. You can have grandiose ideas about others at work, especially the seniors you admire, how they know everything and do everything right. Witnessing their fears and concerns, and their approaches to challenges makes you more impressed by their achievement, you feel like challenges are more approachable, the steps ahead are more attainable. Not that you're any closer clinically, in the skill level, but you feel like a kind of kinship has opened up in a different way.

The program was also an opportunity to address the things that make a cohesive team, that make us all better together. More than before, the whole team stepped up to help each other make it through the day together. For example, if someone on referrals was inundated, you might take their pager or their phone, and say "You deal with the ones you've got, and I'll deal with the next two that come in". Or maybe three people arrive on the ward to be admitted, and someone says, "Okay, you're on admissions, you do two of them, but I'll do one, I've got 10 minutes, I can do that." If someone helps you out, you end up doing the same for someone else. I saw this happening.

A program like this identifies that people want to do something practical to support each other, to build cohesiveness within the team. I think that was one of the best things about it.

*Most Significant Story

Recognising my agency

The most important change brought about by the wellbeing program for me was recognising my agency. I learned there were changes I could make in my workplace environment and my headspace that could improve my wellbeing and the wellbeing of those around me. I was already primed for this change. I had completed exams and was thinking about ways that I could be better at my job, and a better leader and how I could contribute to the unit. Although these changes were dynamic, they happened slowly, like with anything.

Even though I knew it in theory, seeing other people, after the workshops discussing how to give feedback and how to do a good 'power pose' reminded me that we all feel inadequate to the task at hand, and we can all learn to take care of ourselves and others better.

Watching people learn to advocate for themselves around meal breaks, for example made me realise how much there is in these really simple skills. I started noticing people's efforts to communicate, beyond the words they were saying. I hope this means I can respond to people's intended message more explicitly.

Getting doctors to do these sorts of things is really hard. But this experience has taught me that there is a need to learn soft skills, so that we build a workforce which communicates effectively and cares for itself.

Until we sit down and spend time discussing basic things, like meeting our needs, such as taking breaks, we won't develop the necessary skills; people need training in these things.

Taking care of ourselves and supporting each other better

The Wellbeing workshops were a good way to interact online with my colleagues, and to have a chat and share. The wellbeing program helped people to connect. Other changes from the program included encouraging us to maintain our break time; reminding ourselves to drink water, and asking someone to take a break when they have a long shift. For example, we might tell each other that we have to take a break, that we have to go for a lunch break, or go for a water break. We take turns to remind each other: “You have to go, and you should go”.

A main difference for me, is that the program reminded us to take care of ourselves, and to support each other, even on long shifts when we are very stressed at work.

After the program I did look after myself better, and I know where I can get support if I need it. My relationship with colleagues changed because of the program – I had many more interactions. We got to know each other better, and now we support each other better. We have also learnt how to cope with all the things related to isolation.

Role modelling

One of the really positive things about the Wellbeing workshops was that they were led by some of our more senior colleagues. We had time set aside from clinical work where we could just be a group, as opposed to trying to find the time at the end of a long shift or at lunchtime when you still have a pager or a phone. The placing of the workshops into our protected teaching time was really important.

The biggest thing I took from the wellbeing program was the role modelling; senior junior doctors taking ownership and then creating this space where all their colleagues could contribute.

The wellbeing workshops didn't provide me with new knowledge as such, but they made it okay to apply the information that was delivered. They reinforced that my colleagues felt the same way I do when they are overwhelmed or vulnerable. After doing some of the workshops I felt I had more permission to be vulnerable, to ask for help and to say when it wasn't great.

More positive culture at work

When the Wellbeing program began people at work were starting to get tired. The workshops came at a really good time. Since the Wellbeing program there has been a noticeable difference at work. I have been more aware of reminding everyone, as well as myself, to drink water. Everyone has been more mindful of making sure people have time to go and get a drink, or some food and rest.

The workshop about giving feedback; asking for feedback and how to give feedback in a constructive, rather than critical way, I took that on. I will definitely be remembering that in the future. The workshop normalised open conversation, now it isn't something out of the blue that one individual has decided to do, it is something we are all aware of.

There's also a noticeable physical difference. An example is the revamp of our doctor's office, there is new furniture, and plants in there now, it is fresh and more open. We feel welcome; now I've somewhere that I belong at work, somewhere to put my things. And I feel less stressed when I go in that room because it isn't cluttered anymore.

Overall, the general culture at work has changed in a positive way, everyone is more mindful of each other's wellbeing. We feel more comfortable to check in with each other. Previously I'd thought about checking in with someone, but I wasn't sure if it was appropriate, but doing the workshops made me feel it is okay to reach out. Someone checked in on me when they felt I was overwhelmed. They sent a message saying "You sounded a bit down on the phone, is everything okay? You can call me anytime."

I think the positive culture change is the most important.

Courage to be part of the solution

A number of things changed for me as a result of my involvement in the Wellbeing program, my health needs are now a priority, my connection with peers has strengthened, and my courage. I never thought of myself as a brave person: I was the kid who went to theme parks and didn't go on any rides. I thought confidence meant lack of fear; but I have learnt that courage is not the absence of fear–it is the ability to act in the presence of fear. I know now that I am courageous! I also realised if I want the system to change, I need to be part of the solution, and that I can listen, support and help my colleagues.

Being a peer-leader has been a wonderful and valuable experience. I feel I have gained relevant skills and knowledge, while considering the needs of my junior colleagues– whose position I was in only a few years ago. Being involved in a co-designed, peer-led program meant it was not just about attending a two-hour session and then leaving. I have engaged with the resources and followed many threads that I wouldn't have otherwise. At times the responsibility felt a little much, but the support of the team and the overarching belief of senior medical staff in the program was imperative.

Feeling more connected and less alone

The most meaningful aspects of the wellbeing program for me were: the open admission that people were struggling in their own way, acknowledgement that we were all burnt out, tired and angry in some way about some little thing at work, and being able to talk about it. The space created to talk allowed us to hear each other talk about the challenges we were facing; it was okay to admit you were not feeling okay. Some of the people I most look up to, who I thought were perfectly resilient and not phased, shared their struggles and that helped me to feel okay about myself. Also, when I spoke about what I was going through, others then asked me for a coffee, or a meal and shared their version of not being okay. For me the biggest changes, and the greatest outcomes of the wellbeing program were hearing others talk about their experiences and feelings of not being okay, and sharing my experience and feelings. That made me feel more connected and less alone.

Taking breaks, debriefing and being closer to colleagues

The wellbeing program began in the depth of the COVID-19 lockdown.

I used to be quite sceptical about wellbeing programs, but I was at a stage where I thought, 'anything will help'. So, I went to the sessions and tried to take on the advice. The first thing that was really helpful was feeling there was a bit more community; getting to know the people I work with a little more, knowing that they are there, and everyone is in a similar situation, and that my colleagues understand.

There were drinks sent to our staff room, which was amazing. When I forgot my lunch, or it was a busy day and there wasn't time to eat, I was able to drink these 'relatively' nutritious drinks. It was really good.

I made most use of the advice that it's okay to take breaks, that if I take a break my colleagues wouldn't think I was slacking off. Just allowing myself that rest. Colleagues would take my pager, that was really helpful because then I could actually rest, rather than worrying about the pager going off.

I also liked the session on debriefing; learning how and feeling comfortable to debrief with colleagues was very useful. The program provided creative ways to debrief and encouraged people to do it, even when you can't meet face-to-face.

One of the most important things to come out of the program during the pandemic was being closer to colleagues that I don't work with every day, knowing that they are there, and when the pandemic is over we can be together as a group.

I think the combination of all of those things together resulted in the most change for me.

More open lines of communication and learning from each other

A key aspect of the design of the Wellbeing program was that it was peer-led and delivered, this meant the workshop content was relevant for participants, because we were all going through the same event and we could relate to each others' experience. We could share strategies. The program opened up lines of communication across different levels. People felt more comfortable asking for help. It felt like they could come to you and you could go to them. Support networks improved immensely.

The program allowed me, and hopefully my colleagues to make sure we focussed on ourselves as well as other people, so that we could do our job better.

The program also provided me with extra skills in giving and receiving feedback. I made a conscious effort to make sure the members of the team I was working with all left at the same time. It is a long walk to the carpark, and I made use of that time for informal chats and feedback with my colleagues. I would ask them about their shift, and how they felt they went, and I would ask them for feedback on how they thought I had gone. I learnt a lot from my juniors during that time.

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2
Objectives	3	State specific objectives, including any prespecified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	3 – 6
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	5
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	*5*
Bias	9	Describe any efforts to address potential sources of bias	5
Study size	10	Explain how the study size was arrived at	
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5
		(*b*) Describe any methods used to examine subgroups and interactions	5
		(*c*) Explain how missing data were addressed	5
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n/a
		(*e*) Describe any sensitivity analyses	5

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	6
		(b) Give reasons for non-participation at each stage	6
		(c) Consider use of a flow diagram	
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	
		(b) Indicate number of participants with missing data for each variable of interest	
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	6-7
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	*7*
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	7
		(*b*) Report category boundaries when continuous variables were categorized	7
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	8
Discussion			
Key results	18	Summarise key results with reference to study objectives	9
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	11
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	12
Generalisability	21	Discuss the generalisability (external validity) of the study results	12
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	12

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.