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The effect of a proficiency-based progression simulation programme on clinical handover (ISBAR) performance compared to standard training. A randomised controlled trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-025992
Article Type:	Research
Date Submitted by the Author:	18-Aug-2018
Complete List of Authors:	Breen, Dorothy; Cork University Hospital Group, Department of Anaesthesia and Intensive Care; Cork University Hospital O'Brien, Sinead; University College Cork National University of Ireland, School of Nursing and Midwifery McCarthy, Nora; University College Cork National University of Ireland, Medical Education Unit, School of Medicine Gallagher, Anthony; University College Cork National University of Ireland, ASSERT centre Walshe, Nuala; University College Cork National University of Ireland, School of Nursing and Midwifery
Keywords:	MEDICAL EDUCATION & TRAINING, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Handover

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Manuscripts

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3 The effect of a proficiency-based progression simulation programme
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5 on clinical handover (ISBAR) performance compared to standard
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7 training. A randomised controlled trial
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49 Word Count: 3552 including abstract

50
51 Key words: Communication, Patient Handoff, Education, Medical
52
53 Errors, Simulation Training
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1
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3 The effect of a proficiency-based progression simulation programme
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5 on clinical handover (ISBAR) performance compared to standard
6
7 training. A randomised controlled trial.
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10 11 12 13 **ABSTRACT**

14 15 **Objective**

16
17 To determine the effectiveness of a proficiency-based progression
18
19 training approach to clinical handover (ISBAR) compared to standard
20
21 training.
22
23

24 25 **Design**

26
27 A randomised controlled trial with three parallel arms.
28
29

30 31 **Setting**

32
33 A university setting in Ireland
34
35

36 37 **Participants**

38
39 45 third year nursing and 45 final year medical undergraduates
40
41 scheduled to undertake interdisciplinary National Early Warning
42
43 Score (NEWS) training over a three day period in September 2016.
44
45

46 47 **Interventions**

48
49 Participants were prospectively randomised to one of three groups
50
51 before undertaking a performance assessment of an ISBAR
52
53 communication relevant to a deteriorating patient in a high fidelity
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3 simulation facility. The groups were as follows (i) HSE; the national
4
5 Health Service Executive NEWS e-learning programme only, (ii) S;
6
7 the national e-learning programme plus standard simulation, and
8
9 (iii) PBP; the national e-learning programme plus proficiency-based
10
11 progression simulation.
12
13
14

15 16 Main outcome measures

17
18 The primary outcome was the proportion in each group reaching a
19
20 pre-defined proficiency benchmark comprising a series of pre-
21
22 defined steps, errors and critical errors during the performance of a
23
24 standardised, high fidelity simulation assessment case which was
25
26 recorded and independently scored by two independent blinded
27
28 assessors.
29
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31
32

33 34 Results

35
36 6.9% (2/29) HSE group and 13% (3/23) of the S group demonstrated
37
38 proficiency in comparison to 60% (15/25) of PBP group. The
39
40 difference between the HSE and the S group was not statistically
41
42 significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was
43
44 significant for the difference between PBP group and the HSE group
45
46 (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S
47
48 group and the PBP group (Chi-Square = 11.04, CI=0.00-0.00, p =
49
50 0.001).
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Conclusions

Proficiency-based progression is a more effective way to teach ISBAR communication than e-learning either alone or in combination with standard simulation.

Trial Registration

ClinicalTrials.gov Identifier: NCT02886754

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill (handover).
- The performance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
- Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes

Funding Statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests: All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no

1
2
3 support from any organisation for the submitted work, no financial
4
5 relationships with any organisations that might have an interest in
6
7 the submitted work in the previous three years; no other
8
9 relationships or activities that could appear to have influenced the
10
11 submitted work.
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17
18 Ethical Approval: Institutional review board approval was obtained.
19
20 Informed written consent was obtained from all participants.
21
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25
26 Transparency: The lead author affirms that the manuscript is an
27
28 honest, accurate and transparent account of the study being
29
30 reported; that no important aspects have been omitted; and that any
31
32 discrepancies from the study as planned have been explained.
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13 above.
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21 Data sharing: Consent was not obtained for data sharing but the
22
23 presented data are anonymised and risk of identification is low.
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28 **Introduction**

29
30
31 Good clinical communication between health care workers is
32
33 paramount to patient safety. Communication failures are a significant
34
35 source of medical error and preventable adverse events equal if not
36
37 greater than errors due lack of technical skill ^{1, 2, 3}. The need for high
38
39 quality structured communication has become urgent as
40
41 organisations and medical therapies become more complex, patients
42
43 have a greater degree of comorbidity and physicians move towards
44
45 shift patterns of work.
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54 Communication in relation to the acutely deteriorating patient
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56 demands the most efficient, concise and accurate flow of information
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3 amongst healthcare workers of different disciplines for the best
4
5 outcome to be achieved. Many healthcare services and providers
6
7 have adopted the structured communication tool ISBAR (Identify,
8
9 Situation, Background, Assessment, Recommendation) for this
10
11 purpose although several other models exist⁴. The widespread desire
12
13 to use communication tools in clinical practice mandates the need for
14
15 a valid, reliable education and outcomes-based training programme
16
17 to ensure a proficient workforce.
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24 Early Warning Scores facilitate early detection of deterioration by
25
26 categorising a patient's severity of illness and prompting escalation
27
28 of care at specific trigger points utilising a structured communication
29
30 tool such as ISBAR. This enables a more timely response using a
31
32 common language⁵. Ireland was one of the first countries to agree
33
34 and implement a standardised Early Warning Score (The National
35
36 Early Warning Score, NEWS) across the entire acute hospital sector.
37
38 NEWS utilises the ISBAR tool as the recommended structured
39
40 communication tool for the acutely deteriorating patient^{5, 6}. The
41
42 Health Service Executive (HSE) in Ireland recommends the National
43
44 Early Warning Score (NEWS) e-learning education programme as
45
46 part of a mandatory interdisciplinary education programme for all
47
48 healthcare professionals working in acute services. The programme
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3 teaches ISBAR as the recommended tool to escalate care in the
4
5 context of NEWS and the acutely deteriorating patient.
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8
9 Proficiency-based progression (PBP) training is a form of outcome
10 based training that involves training individuals to a "proficiency
11 benchmark." The benchmark is set as the mean performance of
12 clinicians who undertake the procedure regularly in clinical practice.
13
14 It has been shown to improve the performance of individuals
15 undertaking technical procedures (7, 8, 9, 10, 11, 12, 13). This
16 approach has not previously been applied to simulation based
17 training for non-technical skills such as communication.
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30 **Methods**

31 **Objective**

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33
34 The primary aim of the study was to determine the effectiveness on
35
36 ISBAR performance of a proficiency-based progression (PBP)
37 simulation programme when compared with the same simulation
38 programme without the proficiency requirement and compared with
39 the national e-learning programme alone.
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49 **Study design**

50
51 A randomised controlled trial with three parallel arms.
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53

54 **Participants**

1
2
3 Eligible participants were 109 third year nursing and 201 final year
4
5
6 medical students who were scheduled to undertake interdisciplinary
7
8 National Early Warning Score training in September 2016 as part of
9
10 their undergraduate curriculum. This comprised the entire
11
12 undergraduate nursing and medical classes except for 31 medical
13
14 students who were scheduled to undertake this training at a later
15
16 time in the curriculum (figure 1).
17
18
19

20 21 **Interventions**

22
23 All 3rd year nursing and final year medical students were emailed
24
25 prior to training and instructed to undertake the National Early
26
27 Warning Score e-learning programme. Written informed consent
28
29 was obtained from all participants. On the day of training,
30
31 participants were required to submit a certificate of successful
32
33 completion of the e-learning programme. A 15-minute lecture on the
34
35 ISBAR tool was delivered before participants undertook training as
36
37 per their allocated groups. Students were not notified as to which
38
39 study group they were allocated. The study flow is outlined in figure
40
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46
47 2.

48
49 The three training groups were as follows:

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51
52 **(i) e-learning only group (HSE).** Participants in this group
53
54 proceeded directly to the high fidelity suite for performance
55
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1
2
3 assessment. After outcome assessment was complete, participants
4
5 undertook simulation training similar to the S group in order to
6
7 ensure that all students were afforded the same training opportunity.
8
9

10 **(ii) e-learning plus standard simulation group (S).** Participants
11
12 worked in pairs of a medical student and nursing student. If a
13
14 participant did not have a partner, then a non-study peer student was
15
16 asked to pair with that individual for the purposes of training. Data
17
18 from the non-study student was not included in the analysis.
19
20

21
22 Training consisted of a series of simulated phone calls using four
23
24 standardised paper cases for each discipline. Case materials included
25
26 case notes, NEWS charts, and a blank ISBAR template indicating the
27
28 categories and type of information that should be communicated.
29
30 Each scenario had a deteriorating patient event that necessitated an
31
32 ISBAR telephone communication. Participants alternated between
33
34 making and receiving simulated phone calls. A standardised script
35
36 was given to the recipient. Two facilitators conducted the simulation
37
38 training. Both facilitators were experienced clinicians and educators
39
40 who had previously undergone the “Train the Trainer NEWS
41
42 programme” and regularly facilitate NEWS training and healthcare
43
44 simulation. The facilitators offered support and feedback in line with
45
46 standard NEWS training by listening to simulated phone calls and
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3 offering feedback on the ISBAR framework and by answering
4
5 questions as they arose. Participants were required to work through
6
7 all four cases with their partner. Towards the end of the training
8
9 session the participants presented to the facilitator to repeat a
10
11 simulated phone call for either case 3 or 4. The training session was
12
13 3.5 hours in duration, participants were required to stay until the end
14
15 of the training regardless of progress. If an individual had completed
16
17 all the cases, they were asked to assist by continuing to be the
18
19 recipient of phone calls for their partner or by continuing to practice
20
21 by repeating the cases if required.
22
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27

28 **(iii) e-learning plus proficiency-based progression simulation**
29 **group (PBP).** Participants underwent a training programme of the
30
31 same structure, duration, content and facilitator: student ratio as the
32
33 S group. The same two facilitators facilitated both the S and PBP
34
35 training. However in the PBP group, partners scored each other's
36
37 phone calls during training against a series of pre-defined metrics
38
39 (quantified as steps, errors and critical errors for each case) on a
40
41 score sheet to ascertain if the proficiency benchmark for that case
42
43 was reached. Partners shared the results of the metrics and
44
45 proficiency scores with each other as feedback at the end of each
46
47 simulated phone call. If proficiency was not achieved the case was
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3 repeated before progressing to the next case. Participants were
4
5 required to reach proficiency on all four cases with their partner
6
7 before performing case 3 or 4 with the facilitator and demonstrating
8
9 proficiency again. If proficiency was not achieved with the facilitator
10
11 then the participant returned to repeat cases with their partner and
12
13 present for reassessment to the facilitator until proficiency was
14
15 demonstrated.
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22 **Outcomes**

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24
25 The primary outcome was the ability to reach the proficiency
26
27 benchmark on the standardised high-fidelity simulation assessment
28
29 case. The secondary outcomes were the number of successfully
30
31 completed steps, errors and critical errors performed by each group.
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36
37 Performance metrics were developed for the training cases and for
38
39 the high fidelity simulation assessment case as part of a pilot study in
40
41 the previous year. Each case presented a different but commonly
42
43 encountered clinical scenario of an acutely deteriorating patient. The
44
45 metrics were derived for each of the training and assessment cases
46
47 according to the 5 components of the ISBAR tool were specific for
48
49 each case.
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3 The performance metrics were validated through a modified Delphi
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5 expert panel consisting of 9 senior nurses and 8 medical staff who
6
7 regularly facilitate NEWS/ISBAR communication training. Delphi
8
9 panel members reviewed the performance metric for each of the
10
11 simulation cases and the high fidelity performance outcome case and
12
13 metric units were included, excluded or modified by consensus. Each
14
15 metric unit was then classified as a step, error or critical error by
16
17 consensus. The majority of metrics were common to both medicine
18
19 and nursing. The number of metrics per case ranged from 24-26.
20
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25
26 The proficiency benchmark was set as the mean performance of
27
28 qualified personnel from the respective disciplines on each case. Nine
29
30 nursing and five medically qualified practitioners (who regularly
31
32 escalate care in the acute healthcare setting and with a mean years of
33
34 experience=3 years) underwent the high fidelity simulation case. The
35
36 proficiency benchmark for the assessment case was set as the mean
37
38 performance for each discipline as scored by two independent
39
40 assessors.
41
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46
47 Digital recordings of each participant's performance of the
48
49 standardised case in the high fidelity assessment suite were
50
51 reviewed and scored by two independent assessors (experienced
52
53 acute care nurses) using the pre-defined metrics and proficiency
54
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2
3 benchmark. The assessors underwent training on scoring the
4
5 material using 10 recordings of the same case obtained from non-
6
7 study participants. An inter-rater reliability of > 85% was achieved
8
9 prior to commencing scoring study material. The assessors were not
10
11 part of the investigator group, were blinded to the study group
12
13 allocations and had no prior knowledge of any of the participants.
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21 **Sample size**

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23 Power calculation: the numbers needed in each arm was based on
24
25 transfer of training (ToT) observed in previous studies of proficiency
26
27 based progression simulation in surgery and cardiology, where ToT
28
29 rates of 42-69% have been observed ^{7, 8, 9, 10, 11, 12}. In a pilot for the
30
31 current study on 133 medical and nursing students in the previous
32
33 academic year, the TOT was observed to be 16% for the proficiency
34
35 based training group and 3% for the simulation. The pilot however
36
37 was constrained by the existing curriculum, which only allowed for
38
39 90 minutes training time once the e-learning programme was
40
41 complete. In the current study a longer training time (3.5 hours) and
42
43 a more rigorous structure was facilitated. We therefore expected to
44
45 observe an increase in ToT to >40% based on a 3 fold increase in
46
47 objective, blind, assessment of proficiency when compared to the
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3 control group (i.e. 9% for the HSE group vs. 49% for the PBP group).
4
5 A two -tailed test, with n=20 trainees in each group with an alpha of
6
7 5% (which corresponds to a 95% confidence interval) would yield a
8
9 statistical power of 89.9. Therefore 30 (15 medical and 15 nursing
10
11 students) were randomised to each group to allow for drop out rates
12
13 observed in the pilot due to students rescheduling to non-study
14
15 training dates as a result of conflicting demands of their curriculum.
16
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19

20 21 **Randomisation and blinding**

22
23 A de-identified list of nursing and medical student numbers was
24
25 obtained from the School of Nursing and Midwifery and the School of
26
27 Medicine. The lists comprised 109 third year nursing and 201 final
28
29 year medical students scheduled to complete an interdisciplinary
30
31 ISBAR training programme as part of the University undergraduate
32
33 curriculum in September 2016. Randomisation was stratified by
34
35 discipline and was conducted using a computer-generated
36
37 programme (GraphPad) as a two-stage process (figure 1).
38
39
40
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43

44 Firstly n=45 nursing and n=45 medical students were randomly
45
46 selected using the programme. Secondly, participants were randomly
47
48 allocated by discipline using the same computer programme to one
49
50 of the three training groups: HSE, S, and PBP. Subjects were excluded
51
52 from the study if: (i) a certificate of successful completion (within the
53
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1
2
3 previous 4 weeks) of the National Early Warning Score (NEWS) e-
4
5 learning education programme was not presented on the day of
6
7 training, (ii) lack of consent.
8
9

10 Two independent assessors who undertook scoring of performance
11
12 for the assessment case were blinded to student allocations. The
13
14 assessors had no prior knowledge of the students. The participants
15
16 were not informed of the training group to which they were
17
18 allocated.
19
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21
22

23 **Statistical analysis**

24
25 Statistical Analysis was performed with SPSS 22 (Armonk, New
26
27 York). The Kruskal-Wallis test was used to determine if there was a
28
29 statistical difference between groups in relation to the primary end
30
31 point (the numbers reaching proficiency) and the secondary end
32
33 points (the number of completed steps, errors and critical errors).
34
35 The relationship of the three training programmes on proficiency
36
37 was explored using logistic regression analysis.
38
39
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43

44 **Patient and Public Involvement**

45
46 Patients were not involved in the design or conduct of the study.
47
48

49 **Results**

50
51 Baseline characteristics with respect to age, gender, discipline,
52
53 nationality and first language of the participants in each group are
54
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1
2
3 shown in table 1. Figure 3 shows percentages of participants in each
4
5 group who demonstrated the proficiency benchmark following
6
7 assessment in the high fidelity simulation suite. At the end of
8
9 training, 6.9% (2/29) of the e-learning only (HSE) group and 13 %
10
11 (3/23) of the standard simulation (S) group demonstrated
12
13 proficiency. In comparison 60% (15/25) of proficiency-based
14
15 progression simulation (PBP) group were proficient. The difference
16
17 between the HSE and the S group was not statistically significant
18
19 (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant
20
21 for the difference between PBP Group and the HSE Group (Chi-
22
23 Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S group
24
25 and the PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

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36 On logistic regression analysis (figure 4) it was found that in
37
38 comparison to the HSE group, the S group were 2 times as likely to
39
40 demonstrate proficiency, whereas the PBP group were more than 20
41
42 times as likely i.e. the difference between HSE and S groups was not
43
44 statistically different (Ext (B) =2.04, 95% CI=0.31-13.28, p=0.46) but
45
46 was statistically significant for the difference between the PBP and
47
48 HSE groups (Ext (B) =20.25, 95% CI=3.91-105, p<0.000).

1
2
3 The PBP group completed significantly more steps, mean 8.5 (1.7)
4
5 than either the HSE, mean 5.8 (1.6), $p < 0.000$ or S, mean 6.3 (2.1),
6
7 $p < 0.000$ group. Similarly, combined errors and critical errors were
8
9 significantly less in the PBP, mean 3.7 (1.6) than the HSE, mean 5.9
10
11 (2.1), $p < 0.000$ or S, mean 5.2 (1.5), $p < 0.01$ group. Inter-rater
12
13 reliability of the two assessors was 97%.
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20 **Discussion**

21
22
23 Our results shows that addition of a proficiency-based progression
24
25 simulation programme to an e-learning module can deliver a
26
27 superior set of skills for ISBAR communication than an e-learning
28
29 module either alone or in combination with standard simulation.
30
31 Furthermore this benefit is seen with the same resources i.e.
32
33 materials, timeframe, and facilitators as standard simulation. The
34
35 Irish health service like its international counterparts has prioritised
36
37 clinical communication as a key part of the patient safety agenda ^{5, 6,}
38
39 ^{14, 15, 16.} Clinical communication is now viewed as an essential skill
40
41 and training is recommended as mandatory for all health and social
42
43 care professionals ^{6.} All participants were required to produce a
44
45 recent certificate of successful completion of the e-learning
46
47 programme but only 6.9% of the group who undertook the e-learning
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3 module demonstrated the proficiency benchmark. The addition of
4
5 standard simulation did not significantly improve performance with
6
7 only 13% of the S group reaching the benchmark. It could be argued
8
9 that exposure to metrics-based scoring in the practice cases resulted
10
11 in better performance in the assessment case for the PBP group.
12
13 However this is precisely the desired effect i.e. that trainees know
14
15 what skills need to be achieved, practice to achieve them to an
16
17 objective pre-defined standard and transfer that training to a
18
19 dynamic scenario. The S and PBP groups differed in only two
20
21 respects: (i) practice was “repeated” in the S cohort as opposed to
22
23 “deliberate” in PBP cohort i.e. focused on pre-defined metrics and (ii)
24
25 the PBP group was required to reach proficiency benchmarks to
26
27 progress through simulation cases whereas the S group were not.¹⁷
28
29 Our results demonstrate that proficiency-based training can achieve
30
31 skill acquisition rates of the order of 60%, similar to those seen with
32
33 technical skills using this approach. In a study of similar
34
35 experimental design, Angelo et al found that there were 56% fewer
36
37 intraoperative errors and 69% fewer critical errors when compared
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39 to traditional training⁸. To our knowledge our study is the first
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41 randomised trial of proficiency-based progression training of a non-
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43 technical skill.
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3 The main strength of the study is the use of robust methodology to
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5 determine the effectiveness of an educational intervention on
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7 objectively assessed performance outcomes. The study combines the
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9 rigour of a randomised controlled trial with that of an outcomes
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11 based- training approach (proficiency-based progression) to clinical
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13 handover. A significant body of evidence already exists in relation to
14
15 the use of proficiency-based progression for technical skill
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17 acquisition ^{7, 8, 9, 10, 11, 12, 13}. Our results support the use of proficiency-
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19 based progression training for communication skills also.
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21 Weaknesses of the study include the single centre design and the
22
23 application to the undergraduate population only although the
24
25 training programme is designed for use by qualified nurses and
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27 doctors also.
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36 The study was also limited by the restriction on training time. The
37
38 duration of simulation training was extended to 3.5 hours from the
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40 initial pilot (1.5 hours), but was still restricted by the existing
41
42 undergraduate curriculum rather than that which would ideally be
43
44 required to train a fundamental skill. Furthermore skills
45
46 consolidation is an important part of the learning process
47
48 particularly for new skills ¹⁸. In the study by Angelo et al. ⁸ trainees
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50 had a weekend in which to acquire, refine and consolidate their skills
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3 before their proficiency assessment at the end of training. Another
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5 difficulty, which may have impinged on the effectiveness of training,
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7 was the disparity in fidelity between the paper-based training
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9 environment and the assessment undertaken in the high fidelity
10
11 simulation environment. This disparity is challenging for those with
12
13 limited clinical experience such as the undergraduate population.
14
15 Van Sickle et al ⁹ and Gallagher et al ¹⁰ have commented on the
16
17 detrimental impact that this disparity can have on proficiency
18
19 demonstration by trainees.
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25
26 It is now widely recognised that clinical communication skills
27
28 underpin patient safety. Implementation of a training programme in
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30 relation to clinical handover has already been shown to reduce
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32 medical error and preventable adverse events ¹⁹. There is a need for
33
34 valid, reliable, cost efficient clinical handover training programmes to
35
36 address this need and the impact on patient as well as healthcare
37
38 provider outcomes.
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44 **Conclusion**

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46 Proficiency-based progression is a more effective way to teach ISBAR
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48 communication than e-learning either alone or in combination with
49
50 standard simulation.
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Table 1. Demographic characteristics of the three study groups, HSE, S, PBP.

	National e-learning programme (HSE)	National e-learning programme plus, standard simulation training (S)	National e-learning programme plus proficiency based progression simulation training (PBP)	Total
	n=30	n=30	n=30	n=90
Age Group				
18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)
24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)
>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)
Gender				
Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)
Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)
Discipline				
Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Nationality				
Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)
Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)
First Language				
English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)
Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)
Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)
% = % within research group				

Figure legends

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study

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5 progression simulation training for ISBAR performance.
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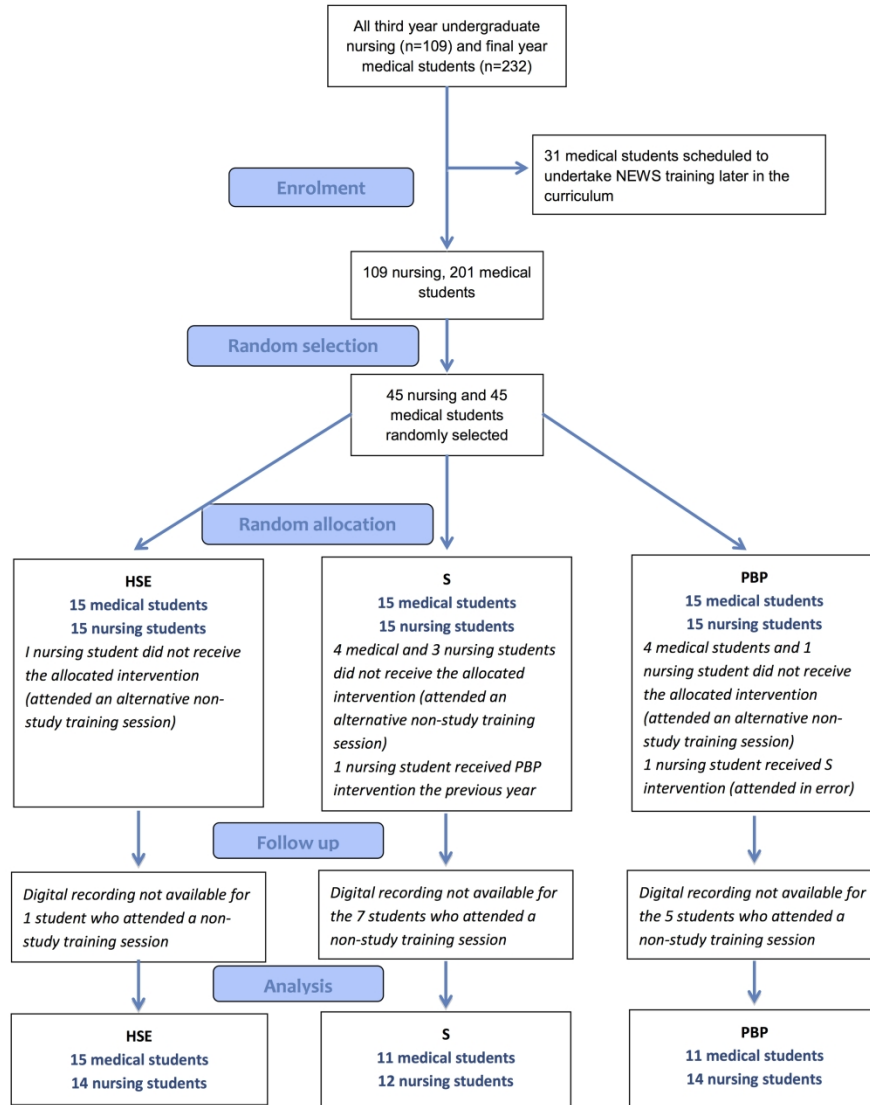
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11 Figure 2. Outline of experimental design and study flow indicating
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13 training interventions and assessment of the three study training
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15 groups of undergraduate medical and nursing participants HSE, S and
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17 PBP.
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24 Figure 3. The percentages reaching the proficiency benchmark at the
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26 end of training of the three study training groups of undergraduate
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28 medical and nursing participants HSE, S and PBP.
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34 Figure 4. Logistic regression analysis for the relative differences
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36 between the three study training groups of undergraduate medical
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38 and nursing participants HSE, S and PBP.
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Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning, standard and proficiency-based progression simulation training for ISBAR performance.

279x361mm (300 x 300 DPI)

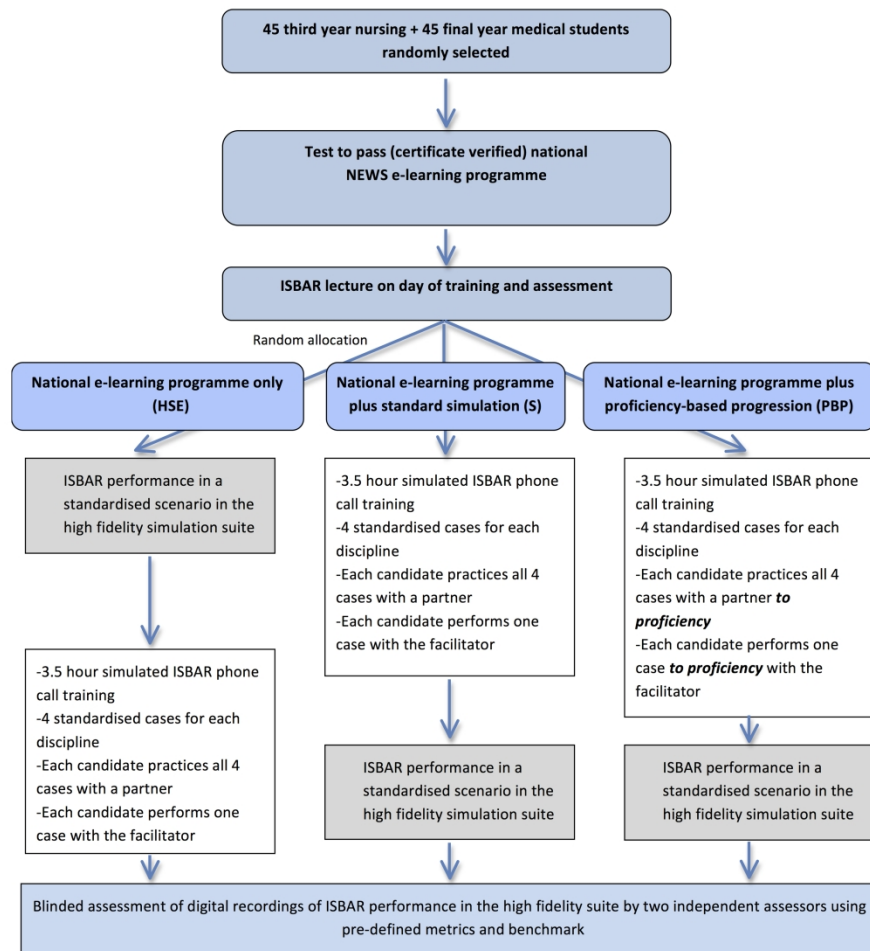


Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

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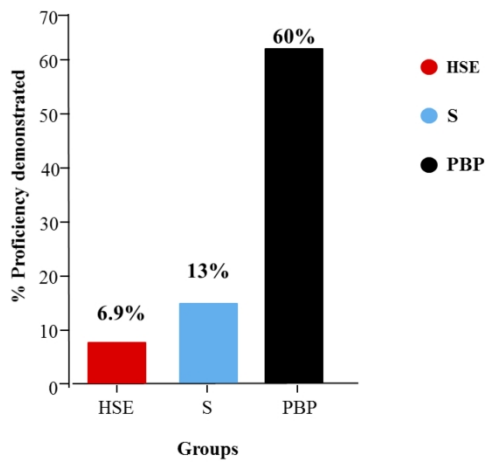


Figure 3. The percentages reaching the proficiency benchmark at the end of training of the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

296x419mm (300 x 300 DPI)

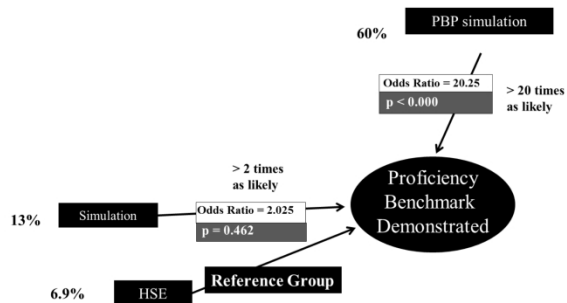


Figure 4. Logistic regression analysis for the relative differences between the three study training groups of undergraduate medical and nursing participants HSE, S and PBP.

296x419mm (300 x 300 DPI)



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8/9/10/11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15,16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	ClinicalTrials.gov NCT02886754
Protocol	24	Where the full trial protocol can be accessed, if available	Attached, Clinical trials.gov,

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and attached
none

Funding 25 Sources of funding and other support (such as supply of drugs), role of funders

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

For peer review only

BMJ Open

The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-025992.R1
Article Type:	Research
Date Submitted by the Author:	25-Feb-2019
Complete List of Authors:	Breen, Dorothy; Cork University Hospital Group, Department of Anaesthesia and Intensive Care O'Brien, Sinead; University College Cork National University of Ireland, School of Nursing and Midwifery McCarthy, Nora; University College Cork National University of Ireland, Medical Education Unit, School of Medicine Gallagher, Anthony; Ulster University , Faculty of Life and Health Sciences Walshe, Nuala; University College Cork National University of Ireland, School of Nursing and Midwifery
Primary Subject Heading:	Communication
Secondary Subject Heading:	Communication, Medical education and training, Nursing
Keywords:	Handover, Simulation, Safety, Communication, Assessment, Performance

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3 The effect of a proficiency-based progression simulation programme
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6 on clinical communication for the deteriorating patient: A
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9 randomised controlled trial.

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47 *Ireland. Tel 00353-21-4546434, Fax 00353-21 4922135*

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52 Word Count: 3799 including abstract

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55 Key words: Medical Education and Training, Handover, Simulation,
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14 **ABSTRACT**

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17 **Objective**

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19 To determine the effectiveness of a proficiency-based progression
20 training approach to clinical communication in the context of a
21 clinically deteriorating patient.
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28 **Design**

29
30 A randomised controlled trial with three parallel arms.
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34 **Setting**

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36 A university setting in Ireland
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40 **Participants**

41 45 third year nursing and 45 final year medical undergraduates
42 scheduled to undertake interdisciplinary National Early Warning
43 Score (NEWS) training over a three day period in September 2016.
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50 **Interventions**

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52 Participants were prospectively randomised to one of three groups
53 before undertaking a performance assessment of the ISBAR
54 communication tool (Identification, Situation, Background,
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3 Assessment, Recommendation) relevant to a deteriorating patient in
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6 a high fidelity simulation facility. The groups were as follows (i) E;
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9 the Irish Health Service national NEWS e-learning programme only,
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12 (ii) E+S; the national e-learning programme plus standard
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15 simulation, and (iii) E+PBP; the national e-learning programme plus
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18 proficiency-based progression simulation.

19 20 Main outcome measures

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22 The primary outcome was the proportion in each group reaching a
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25 pre-defined proficiency benchmark comprising a series of pre-
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28 defined steps, errors and critical errors during the performance of a
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31 standardised, high fidelity simulation assessment case which was
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34 recorded and independently scored by two independent blinded
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37 assessors.

38 39 Results

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41 6.9% (2/29) of the E group and 13% (3/23) of the E+S group
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44 demonstrated proficiency in comparison to 60% (15/25) of the
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46
47 E+PBP group. The difference between the E and the E+S groups was
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50 not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p=
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53 0.63) but was significant for the difference between the E and the E
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56 +PBP groups (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and
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3 between the E+S and the E+PBP groups (Chi-Square = 11.04,
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6 CI=0.00-0.00, p = 0.001).
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8 9 **Conclusions**

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11 Proficiency-based progression is a more effective way to teach
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13 clinical communication in the context of the deteriorating patient
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15 than e-learning either alone or in combination with standard
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17 simulation.
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21 22 **Trial Registration**

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25 ClinicalTrials.gov Identifier: NCT02886754
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28 29 **STRENGTHS AND LIMITATIONS OF THE STUDY**

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- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill.
 - The performance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
 - Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes.

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Funding Statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

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6 Competing interests: All authors have completed the ICMJE uniform
7
8 disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no
9
10 support from any organisation for the submitted work, no financial
11
12 relationships with any organisations that might have an interest in
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14 the submitted work in the previous three years; no other
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16 relationships or activities that could appear to have influenced the
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18 submitted work.
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28 Ethical Approval: Institutional review board approval was obtained.
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30 Informed written consent was obtained from all participants.
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36 Transparency: The lead author affirms that the manuscript is an
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38 honest, accurate and transparent account of the study being
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40 reported; that no important aspects have been omitted; and that any
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42 discrepancies from the study as planned have been explained.
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28 All authors listed below met ICMJE criteria for contributorship as
29
30 outlined below.
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36 1. Contributed substantially to the conception and design of the work;
37
38 the acquisition, of the data for the work; AND
39
40

41 2. Drafting the work, revising the work critically for important
42
43 intellectual content AND
44
45

46 3. Drafting the final version to be published; AND
47
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49 4. Agrees to be accountable for all aspects of the work in ensuring
50
51 that questions related to the accuracy or integrity of any part of the
52
53 work are appropriately investigated and resolved.
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- 3 1. Contributed substantially to the conception and design of the
- 4
- 5 work; and the acquisition, of data for the work; AND
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- 14 4. Agrees to be accountable for all aspects of the work in ensuring
- 15
- 16 that questions related to the accuracy or integrity of any part of the
- 17
- 18 work are appropriately investigated and resolved.
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- 26
- 27 work; and the acquisition, AND
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- 39 5. Agrees to be accountable for all aspects of the work in ensuring
- 40
- 41 that questions related to the accuracy or integrity of any part of the
- 42
- 43 work are appropriately investigated and resolved.
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- 51
- 52 work; and the analysis and interpretation of data for the work; AND
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3 3. Final approval of the version to be published; AND

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5
6 Agreement to be accountable for all aspects of the work in 4. Agrees
7
8 to ensure that questions related to the accuracy or integrity of any
9
10 part of the work are appropriately investigated and resolved.
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18
19 work; and the acquisition, of data for the work; AND
20
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22 2. Revising the work critically for important intellectual content;
23
24

25 AND
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27
28 3. Final approval of the version to be published; AND
29

30
31 4. Agrees to be accountable for all aspects of the work in ensuring
32
33 that questions related to the accuracy or integrity of any part of the
34
35 work are appropriately investigated and resolved.
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40
41 Data Sharing: Deidentified individual participant data that underlie
42
43 the results published in this article as well as study protocol,
44
45 statistical analysis plan and analytical code will be made available on
46
47 request beginning three months and ending 5 years after publication
48
49 to researchers who provide a methodologically sound proposal.
50
51 Please direct requests to the corresponding author. Data accessors
52
53 will need to sign a data access agreement. The data from the pilot
54
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1
2
3 study and from this study in relation to learner perceptions is
4
5
6 undergoing analysis and will be available following publication.
7
8
9

10 11 **Introduction**

12
13
14
15 Simulation-based training is being increasingly deployed for both
16
17 technical and non-technical skill acquisition in healthcare with the
18
19 aim of reducing medical error and patient harm. There is a need for
20
21 an evidence-based approach to such training to ensure that the
22
23 resources utilised can reliably deliver a quantifiable improved skill
24
25 set rather than just an enhanced educational experience. Proficiency-
26
27 based progression (PBP) training is a form of outcomes-based
28
29 training that involves training individuals to a "proficiency
30
31 benchmark." Trainees undertake deliberate (rather than repeated)
32
33 practice to demonstrate a pre-defined set of metrics. The proficiency
34
35 benchmark is set as the mean performance of clinicians who
36
37 undertake the procedure regularly in clinical practice. It has been
38
39 shown to improve the performance of individuals undertaking
40
41 technical procedures ^{1, 2, 3, 4, 5, 6, 7}. Metrics are operationally defined to
42
43 facilitate objective scoring. For example in the study by Cates et al
44
45 demonstrating improved performance of carotid angiography, pre-
46
47 defined metric errors include "number of diagnostic catheters used
48
49
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1
2
3 to obtain diagnostic pictures” and “catheter advancing without a
4
5
6 guide-wire in front of it”⁶. Despite these results, PBP methodology
7
8
9 has not previously been applied to simulation-based training for non-
10
11
12 technical skills yet communication failures are a significant source of
13
14
15 medical error and preventable adverse events equal if not greater
16
17 than errors due to lack of technical skill ^{8, 9, 10}. Escalation of care for
18
19
20 an acutely deteriorating patient demands the most efficient, concise
21
22
23 and accurate flow of information amongst healthcare workers of
24
25
26 different disciplines for the best outcome to be achieved.

27
28
29 Early Warning Scores facilitate early detection of deterioration by
30
31
32 categorising a patient’s severity of illness and prompting escalation
33
34
35 of care at specific trigger points utilising a structured communication
36
37
38 tool such as ISBAR (Identification, Situation, Background,
39
40
41 Assessment, Recommendation). This enables a more timely response
42
43
44 using a common language ¹¹. Ireland was one of the first countries to
45
46
47 agree and implement a standardised Early Warning Score (The
48
49
50 National Early Warning Score, NEWS) across the entire acute hospital
51
52
53 sector. NEWS utilises the ISBAR tool as the recommended structured
54
55
56 communication tool for the acutely deteriorating patient ^{12, 13}. The
57
58
59 National Early Warning Score (NEWS) e-learning education
60
programme is recommended as the national interdisciplinary

1
2
3 education programme for all healthcare professionals working in
4
5
6 acute services. The programme teaches ISBAR as the standardised
7
8
9 tool to escalate care in the context of the acutely deteriorating
10
11
12 patient.

13
14
15 The primary aim of this study was to determine if the addition of a
16
17
18 proficiency-based progression simulation training programme to the
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20
21 national NEWS e-learning module results in better performance of
22
23
24 clinical communication of a deteriorating patient than either the e-
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26
27 learning module alone or in combination with standard simulation.
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30

31 **Methods**

32 **Study design**

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34
35 A randomised controlled trial with three parallel arms.
36
37

38 **Participants**

39
40
41 Eligible participants were 109 third year nursing and 201 final year
42
43
44 medical students who were scheduled to undertake interdisciplinary
45
46
47 National Early Warning Score training in September 2016 as part of
48
49
50 their undergraduate curriculum. This comprised the entire
51
52
53 undergraduate nursing and medical classes except for 31 medical
54
55
56 students who were scheduled to undertake this training at a later
57
58
59 time in the curriculum (figure 1).
60

Interventions

All 3rd year nursing and final year medical students were emailed prior to training and instructed to undertake the National Early Warning Score e-learning programme. Written informed consent was obtained from all participants. On the day of training, participants were required to submit a certificate of successful completion of the e-learning programme. A 15-minute lecture on the ISBAR tool was delivered before participants undertook training as per their allocated groups. Students were not notified as to which study group they were allocated. The study flow is outlined in figure 2.

The three training groups were as follows:

(i) e-learning only group (E). Participants in this group proceeded immediately following the 15-minute lecture to the high fidelity suite for performance assessment. After outcome assessment was complete, participants undertook simulation training similar to the E+S group as outlined below in order to ensure that all students were afforded the same training opportunity from a curriculum perspective.

(ii) e-learning plus standard simulation group (E+S). Participants worked in pairs of a medical student and nursing student. If a

1
2
3 participant did not have a partner, then a non-study peer student was
4
5
6 asked to pair with that individual for the purposes of training. Data
7
8
9 from the non-study student was not included in the analysis.

10
11 Training consisted of a series of simulated phone calls using four
12
13
14 standardised paper cases for each discipline. Case materials included
15
16
17 case notes, NEWS charts, and a blank ISBAR template indicating the
18
19
20 categories and type of information that should be communicated.
21
22
23 Each scenario had a deteriorating patient event that necessitated an
24
25
26 ISBAR telephone communication. Participants alternated between
27
28
29 making and receiving simulated phone calls. A standardised script
30
31
32 was given to the recipient. Two facilitators conducted the simulation
33
34
35 training. Both facilitators were experienced clinicians and educators
36
37
38 who had previously undergone the “Train the Trainer NEWS
39
40
41 programme” and regularly facilitate NEWS training and healthcare
42
43
44 simulation. The facilitators offered support and feedback in line with
45
46
47 standard NEWS training by listening to simulated phone calls and
48
49
50 offering feedback on the ISBAR framework and by answering
51
52
53 questions as they arose. Participants were required to work through
54
55
56 all four cases with their partner. Towards the end of the training
57
58
59 session the participants presented to the facilitator to repeat a
60
simulated phone call for either case 3 or 4. The training session was

1
2
3 3.5 hours in duration, participants were required to stay until the end
4
5
6 of the training regardless of progress. If an individual had completed
7
8
9 all the cases, they were asked to assist by continuing to be the
10
11 recipient of phone calls for their partner or by continuing to practice
12
13 by repeating the cases if required.
14
15

16
17 **(iii) e-learning plus proficiency-based progression simulation**
18
19 **group (E+PBP).** Participants underwent a training programme of
20
21 the same structure, duration (3.5 hours), content and facilitator:
22
23 student ratio as the E+S group. The same two facilitators facilitated
24
25 both the E+S and E+PBP training. However in the E+PBP group,
26
27 partners scored each other's phone calls during training against a
28
29 series of pre-defined metrics (quantified as steps, errors and critical
30
31 errors for each case) on a score sheet to ascertain if the proficiency
32
33 benchmark for that case was reached. Partners shared the results of
34
35 the metrics and proficiency scores with each other as feedback at the
36
37 end of each simulated phone call. If proficiency was not achieved the
38
39 case was repeated before progressing to the next case. Participants
40
41 were required to reach proficiency on all four cases with their
42
43 partner before performing case 3 or 4 with the facilitator and
44
45 demonstrating proficiency again. If proficiency was not achieved with
46
47 the facilitator then the participant returned to repeat cases with their
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3 partner and present for reassessment to the facilitator until
4
5
6 proficiency was demonstrated. The training session was 3.5 hours in
7
8
9 duration, participants were required to stay until the end of the
10
11 training regardless of progress. If an individual had completed all the
12
13 cases, they were asked to assist by continuing to be the recipient of
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15 phone calls for their partner or by continuing to practice by repeating
16
17 the cases if required.
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26 **Outcomes**

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30 The primary outcome was the ability to reach the proficiency
31
32 benchmark on the standardised high-fidelity simulation assessment
33
34 case. The secondary outcomes were the number of successfully
35
36 completed steps, errors and critical errors performed by each group.
37
38
39
40
41

42 Performance metrics were developed for the training cases and for
43
44 the high fidelity simulation assessment case as part of a pilot study in
45
46 the previous year. Each case presented a different but commonly
47
48 encountered clinical scenario of an acutely deteriorating patient. As
49
50 an example, the outline of the nursing component of the high fidelity
51
52 simulation assessment case is shown in figure 3.
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3 The metrics were derived for each of the training and assessment
4 cases according to the 5 components of the ISBAR tool and were
5 specific to each case.
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12 The performance metrics were validated through a modified Delphi
13 expert panel consisting of 9 senior nurses and 8 medical staff who
14 regularly facilitate NEWS/ISBAR communication training. Delphi
15 panel members reviewed the performance metric for each of the
16 simulation cases and the high fidelity performance outcome case and
17 metric units were included, excluded or modified by consensus. Each
18 metric unit was then classified as a step, error or critical error by
19 consensus. The majority of metrics were common to both medicine
20 and nursing. The number of metrics per case ranged from 24-26.
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37 The proficiency benchmark was set as the mean performance of
38 qualified personnel from the respective disciplines on each case. Nine
39 nursing and five medically qualified practitioners (who regularly
40 escalate care in the acute healthcare setting and with a mean years of
41 experience=3 years) underwent the high fidelity simulation case. The
42 proficiency benchmark for the assessment case was set as the mean
43 performance for each discipline as scored by two independent
44 assessors using the pre-defined metrics. An extract from the metric
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3 scoring sheet and proficiency benchmark for the high fidelity
4 simulation assessment case is shown in figure 4.
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6

7
8 Digital recordings of each participant's performance of the
9 standardised case in the high fidelity assessment suite were
10 reviewed and scored by two independent assessors (experienced
11 acute care nurses) using the pre-defined metrics and proficiency
12 benchmark.
13
14

15
16 The assessors underwent training on scoring the material using 10
17 recordings of the same case obtained from non-study participants.
18 Assessment of the digital recordings was undertaken within 2
19 months of study participation. An inter-rater reliability of > 85% was
20 achieved prior to commencing scoring study material. The assessors
21 were not part of the investigator group, were blinded to the study
22 group allocations and had no prior knowledge of any of the
23 participants.
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47 **Sample size**

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49 Power calculation: the numbers needed in each arm was based on
50 transfer of training (the degree to which trainees transfer the
51 knowledge and skills acquired from one learning situation to another
52 setting) observed in previous studies of proficiency based
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1
2
3 progression simulation in surgery and cardiology, where transfer of
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5 training rates of 42-69% have been observed ^{1, 2, 3, 4, 5, 6}. In a pilot for
6
7 the current study on 133 medical and nursing students in the
8
9 previous academic year, the transfer of training rate was observed to
10
11 be 16% for the proficiency based training group and 3% for the
12
13 standard simulation group. The pilot however was constrained by
14
15 the existing curriculum, which only allowed for 90 minutes training
16
17 time once the e-learning programme was complete. In the current
18
19 study a longer training time (3.5 hours) and a more rigorous
20
21 structure was facilitated. We therefore expected to observe an
22
23 increase in transfer of training to >40% based on a 3 fold increase in
24
25 objective, blind, assessment of proficiency when compared to the
26
27 control group (i.e. 9% for the E group vs. 49% for the E+PBP group).
28
29 A two -tailed test, with n=20 trainees in each group with an alpha of
30
31 5% (which corresponds to a 95% confidence interval) would yield a
32
33 statistical power of 89.9. Therefore 30 (15 medical and 15 nursing
34
35 students) were randomised to each group to allow for drop out rates
36
37 observed in the pilot due to students rescheduling to non-study
38
39 training dates as a result of conflicting demands of their curriculum.
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55 **Randomisation and blinding**

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3 A de-identified numbered list of nursing and medical student
4 numbers was obtained from the School of Nursing and Midwifery and
5
6 the School of Medicine. The lists comprised 109 third year nursing
7
8 and 201 final year medical students scheduled to complete an
9
10 interdisciplinary ISBAR training programme as part of the University
11
12 undergraduate curriculum in September 2016. Randomisation was
13
14 stratified by discipline and was conducted using a computer-
15
16 generated programme (GraphPad QuickCals software package,
17
18 www.graphpad.com/quickcalcs/) as a two-stage process (figure 1).
19
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27
28 Firstly n=45 nursing and n=45 medical students were randomly
29
30 selected using the programme. These 90 students were then
31
32 randomly allocated by discipline using the same computer
33
34 programme to one of the three training groups: E, E+S, and E+PBP.
35
36 Subjects were excluded from the study if: (i) a certificate of
37
38 successful completion (within the previous 4 weeks) of the National
39
40 Early Warning Score (NEWS) e-learning education programme was
41
42 not presented on the day of training, (ii) lack of consent.
43
44
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52 **Statistical analysis**

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54
55 Statistical Analysis was performed with SPSS 22 (Armonk, New
56
57 York). The Kruskal-Wallis test was used to determine if there was a
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59
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1
2
3 statistical difference between groups in relation to the primary end
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5
6 point (the numbers reaching proficiency) and the secondary end
7
8
9 points (the number of completed steps, errors and critical errors).
10
11 The relationship of the three training programmes on proficiency
12
13
14 was explored using logistic regression analysis.
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16

17 Patient and Public Involvement

18
19 Patients were not involved in the design or conduct of the study.
20
21

22 Results

23
24 Baseline characteristics with respect to age, gender, discipline,
25
26 nationality and first language of the participants in each group are
27
28 shown in table 1.
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39 Table 1

Study Group		E ^a	E+S ^b	E+PBP ^c	Total	prob. level [#]
		n=30	n=30	n=30	n=90	
Discipline	Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)	
	Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)	
Age Group	18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)	p = 0.853
	24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)	
	>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)	
Gender	Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)	p = 0.919
	Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)	
Nationality	Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)	p = 0.664
	Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)	
First Language	English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)	p = 0.223
	Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)	
	Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)	

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Figure 5 shows percentages of participants in each group who demonstrated the proficiency benchmark following assessment in the high fidelity simulation suite. At the end of training, 6.9% (2/29) of the e-learning only (E) group and 13 % (3/23) of the standard simulation (E+S) group demonstrated proficiency. In comparison 60% (15/25) of proficiency-based progression simulation (E+PBP) group were proficient. The difference between the E group and the E+S group was not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p= 0.63) but was significant for the difference between E group and the E +PBP group (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and between the S group and the E+PBP group (Chi-Square = 11.04, CI=0.00-0.00, p = 0.001).

On logistic regression analysis (figure 6) it was found that in comparison to the E group, the E+S group were 2 times as likely to demonstrate proficiency (Ext (B) =2.04, 95% CI=0.31-13.28, p=0.46). This difference was in the direction of improved performance but the effect was not statistically significant probably because of the sample size used in this study. In contrast the PBP trained group were more than 20 times as likely to demonstrate proficiency in comparison to

1
2
3 the E trained group and the difference was statistically significant
4
5
6 (Ext (B) =20.25, 95% CI=3.91-105, $p<0.000$).
7

8
9 The E+PBP group completed significantly more steps, mean 8.5 (1.7)
10
11 than either the E, mean 5.8 (1.6), $p<0.000$ or E+S groups, mean 6.3
12
13 (2.1), $p<0.000$ group. Similarly, combined errors and critical errors
14
15 were significantly less in the E+PBP, mean 3.7 (1.6) than either the E,
16
17 mean 5.9 (2.1), $p<0.000$ or the E+S groups, mean 5.2 (1.5), $p<0.01$
18
19 group. Inter-rater reliability of the two assessors was 97%.
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25

26 **Discussion**

27
28
29 Our results show that addition of a proficiency-based progression
30
31 simulation programme to an e-learning module can deliver a
32
33 superior set of skills for ISBAR communication in relation to a
34
35 deteriorating patient than an e-learning module either alone or in
36
37 combination with standard simulation. Furthermore this benefit is
38
39 seen within the same resources i.e. materials, timeframe, and
40
41 facilitators as standard simulation. The Irish health service like its
42
43 international counterparts has prioritised clinical communication as
44
45 a key part of the patient safety agenda ^{12, 13, 14, 15, 16}. Clinical
46
47 communication is now viewed as an essential skill and training is
48
49 recommended as mandatory for all health and social care
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professionals¹³. All participants were required to produce a recent certificate of successful completion of the e-learning programme but only 6.9% of the group who undertook the e-learning module only demonstrated the proficiency benchmark. The addition of standard simulation did not significantly improve performance with only 13% of the E+S group reaching the benchmark. It could be argued that exposure to metrics-based scoring in the practice cases resulted in better performance in the assessment case for the E+PBP group. However this is precisely the desired effect i.e. that trainees know what skills need to be achieved, practice to achieve them to an objective pre-defined standard and transfer that training to a dynamic scenario. The E+S and E+PBP groups differed in only two respects: (i) practice was “repeated” in the E+S cohort as opposed to “deliberate” in E+PBP cohort i.e. focused on pre-defined metrics and (ii) the E+PBP group was required to reach proficiency benchmarks to progress through simulation cases whereas the E+S group were not. Our results demonstrate that proficiency-based training can achieve skill acquisition rates of the order of 60%, similar to those seen with technical skills using this approach. In a study of similar experimental design, Angelo et al found that there were 56% fewer intraoperative errors and 69% fewer critical errors when compared

1
2
3 to traditional training ². To our knowledge our study is the first
4
5
6 randomised trial of proficiency-based progression training of a non-
7
8
9 technical skill.

10
11 The main strength of the study is the use of robust methodology to
12
13 determine the effectiveness of an educational intervention on
14
15 objectively assessed performance outcomes. The study combines the
16
17 rigour of a randomised controlled trial with that of an outcomes
18
19 based- training approach (proficiency-based progression) to clinical
20
21 communication. A significant body of evidence already exists in
22
23 relation to the use of proficiency-based progression for technical skill
24
25 acquisition ^{7, 8, 9, 10, 11, 12, 13}. Our results support the use of proficiency-
26
27 based progression training for communication skills also. This study
28
29 indicates that the impact of a PBP training methodology appears to
30
31 be >40% for non-technical as well as technical skills.
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41 Weaknesses of the study include the single centre design and the
42
43 application to the undergraduate population only, although the
44
45 training programme was designed for qualified nurses and doctors
46
47 also. Since the completion of study, the programme has been applied
48
49 successfully to both nursing and medical undergraduate programmes
50
51 in the university setting and to doctors in training in the hospital
52
53 setting. There is a need for further robust evaluation of this
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1
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3 application of the programme and extension to other sites and
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6 clinical settings.
7

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9 The study was limited by the restriction on training time. The
10
11 duration of simulation training for both E+S and the E+PBP groups
12
13 was extended to 3.5 hours from the initial pilot (1.5 hours), but was
14
15 still restricted by the existing undergraduate curriculum rather than
16
17 that which would ideally be required to train a fundamental skill.
18
19 Skills consolidation is an important part of the learning process
20
21 particularly for new skills¹⁷. In the study by Angelo et al.² trainees
22
23 had a weekend in which to acquire, refine and consolidate their skills
24
25 before their proficiency assessment at the end of training. Another
26
27 difficulty, which may have impinged on the effectiveness of training,
28
29 was the disparity in fidelity between the paper-based training
30
31 environment and the assessment undertaken in the high fidelity
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33 simulation environment. This disparity is challenging for those with
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35 limited clinical experience such as the undergraduate population.
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37 Van Sickle et al³ and Gallagher et al⁴ have commented on the
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39 detrimental impact that this disparity can have on proficiency
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41 demonstration by trainees.
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55 It is now widely recognised that clinical communication skills
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57 underpin patient safety. Implementation of a training programme in
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3 relation to clinical communication has already been shown to reduce
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6 medical error and preventable adverse events ¹⁸. There is a need for
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9 valid, reliable, cost efficient clinical communication training
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12 programmes to address this need and the impact on patient as well
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14
15 as healthcare provider outcomes.

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17 In summary, our study shows that proficiency-based progression is a
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19
20 more effective way to teach clinical communication for the
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22
23 deteriorating patient than e-learning either alone or in combination
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26 with standard simulation.

30 31 **References**

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36 37 38 39 40 41 42 43 44 **Legends**

45
46
47 Table 1. Demographic characteristics of the three study groups: e-
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49 learning alone (E), e-learning plus standard simulation (E+S) and e-
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51 learning plus proficiency-based progression simulation (E+PBP) .
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Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

Figure 3. Outline of the high fidelity simulation performance assessment case for nursing undergraduates

Figure 4. Extract from the nursing metric scoring sheet illustrating some of the metrics and the proficiency benchmark for the high fidelity simulation assessment case.

Figure 5. The percentages reaching the proficiency benchmark at the end of training of the three study training groups; e-learning alone

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3 (E), e-learning plus standard simulation training (E+S) and e-learning
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6 plus proficiency-based progression simulation training (E+PBP).
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11 Figure 6. Logistic regression analysis for the relative differences
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14 between the three study training groups of undergraduate medical
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17 and nursing participants; E, E+S and E+PBP.
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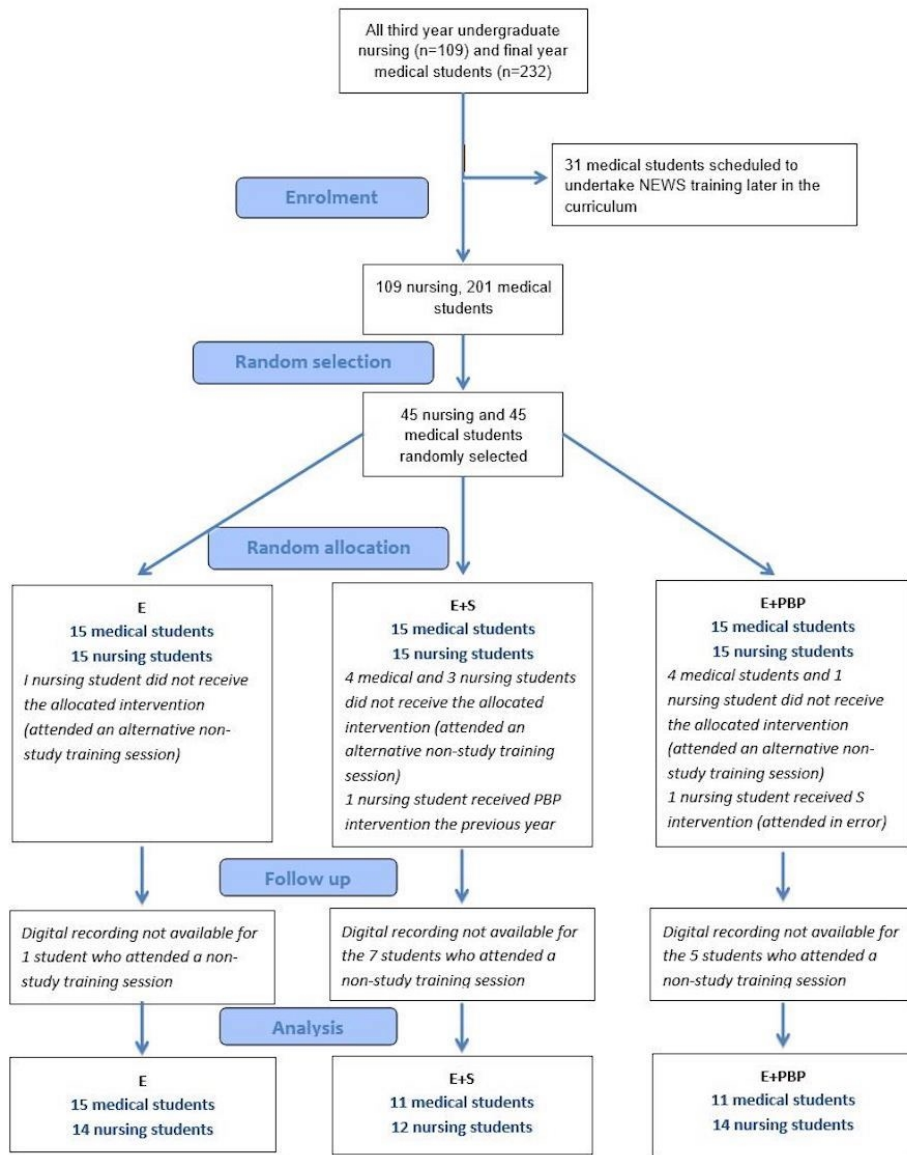


Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

76x98mm (300 x 300 DPI)

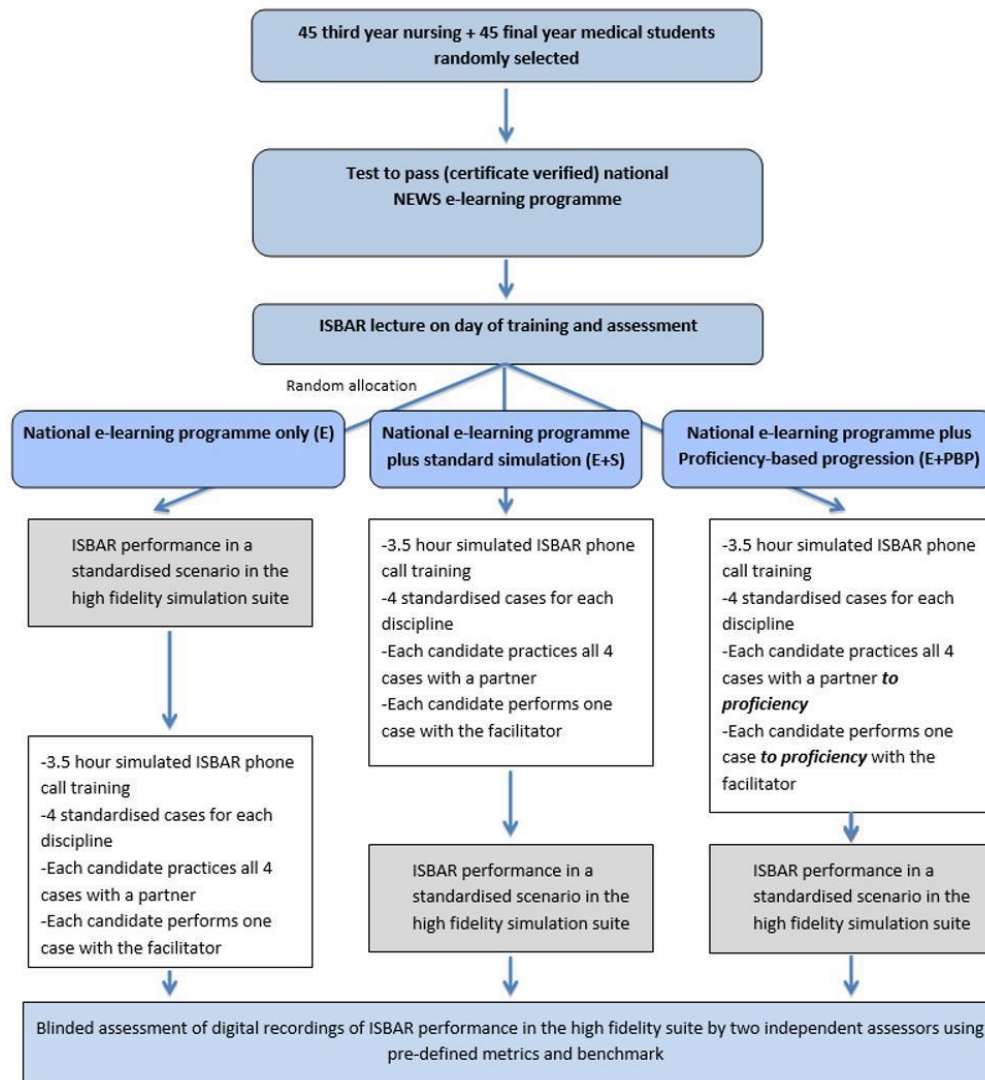
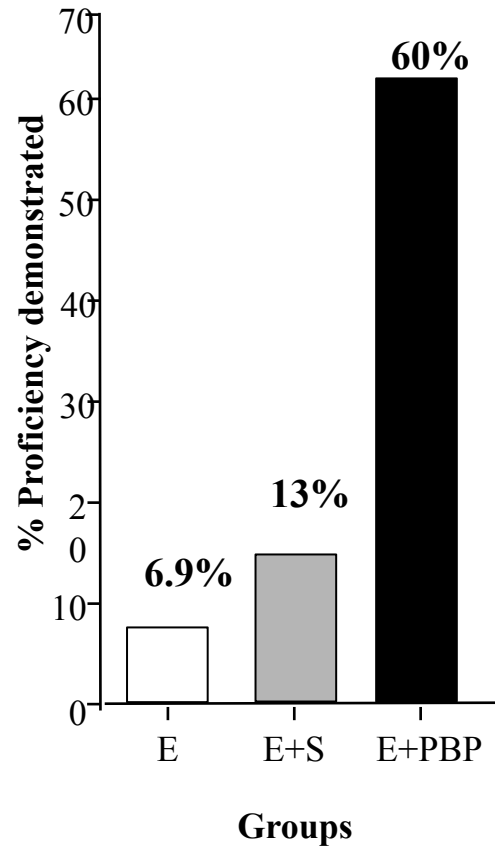


Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

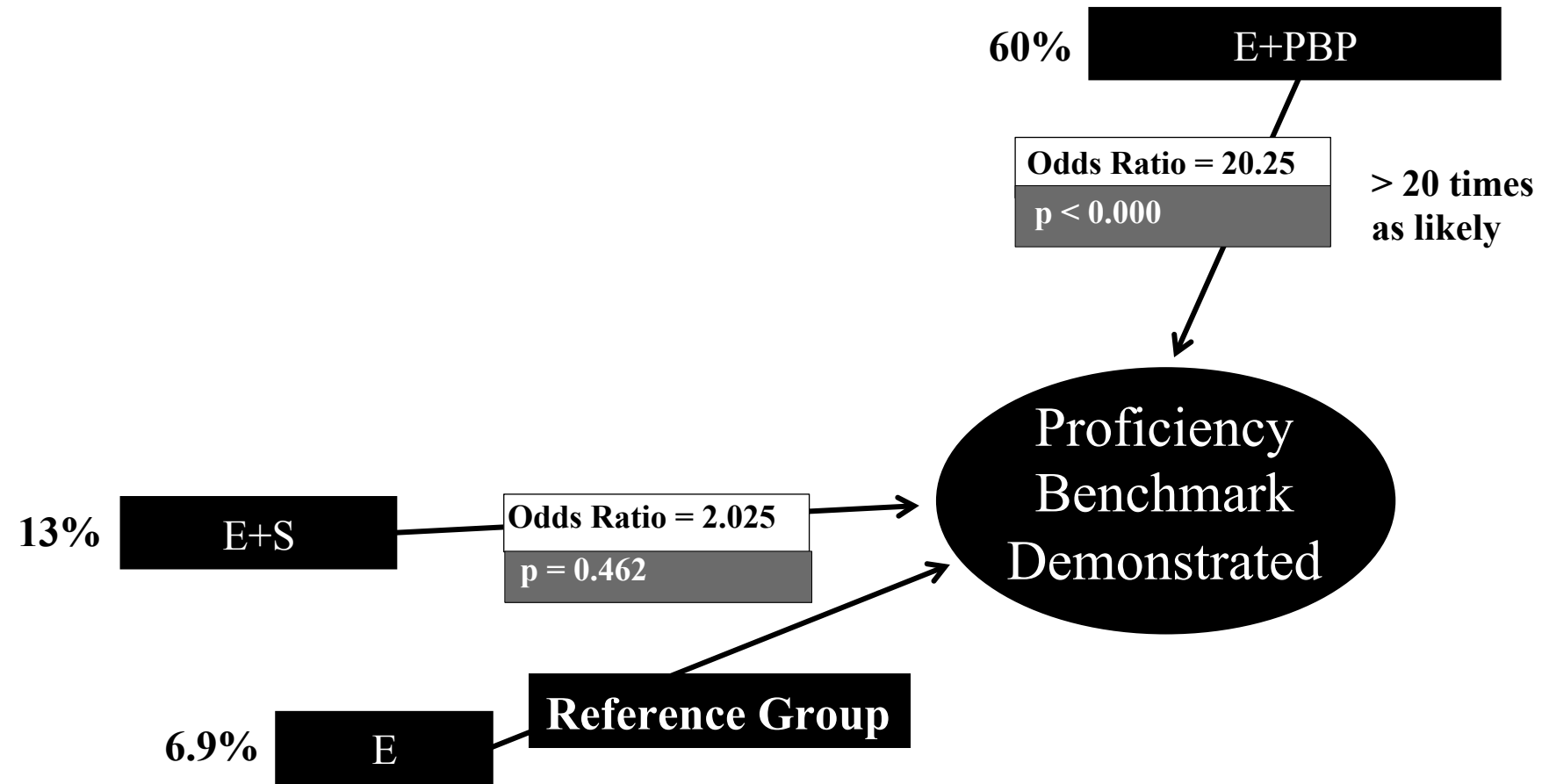
82x90mm (300 x 300 DPI)

Simulator Parameters		Roleplayer vocals	Escalation Call	
2	RR	21	2 days post laparotomy	
3	SpO ₂	96%	you feel very tired and weak	
4	oxygen	Room Air	you think you should be feeling better than you are	
5	BP	92/58	Do not ask any questions or provide any information throughout this phone-call except to answer the below questions	
6	HR	98	you thought you would be improving at this stage	
7	AVPU	Alert	if asked you feel your pain is less controlled than yesterday	
8	Temp	36.7	you are still nil by mouth	
9	EWS	5	you now have a temporary ileostomy and are a quite upset about this, but know it will hopefully be reversed in the future	
10	Cardiac monitor	Sinus tachycardia (if attached to CM)		
11	Cap refill	less than 2sec		
12	skin	pink, warm, dry		
13	Urinary output (0.5ml/kg/hr)	20mls last hour	If recipient name not confirmed, and you are asked "is this the intern/SHO/reg?"	
14	IV site	VIP = 0 [visual infusion phlebitis score]	If asked for any recommendation	
15	IV hydration	125mls/hr	If told "I think she is bleeding/needs review/has sepsis"	
16	Pain	Student to assess if asked for PCA - 32mls in syringe; 35 demands, 18 successful]	If asked "Will you review her?"	
17	Bowel sounds	Student to assess absent	If asked "When will you review her?"	
18	Abdomen	wound - assess independently drain assess independently ileostomy : assess independently distension yes abdomen is distended	If told "Her EWS is (3-7), so you must review her in 30mins"	
19	Blood Loss	If students enquire requiring volume in drain/ileostomy - say "you may assess independently" If students pick up a jug to empty either give them the relevant volume " there are 250mls in the drain " " there are 100mls in the ileostomy "	If asked "Will you review her in 30 minutes/straight away?"	
20	Chest sounds	normal		
21	Cap blood sugar	5.8mmol/L		

Extract from Nursing Simulation Metric					
			Tick if present	Tick if present	Tick if present
16	S	States the situation <i>There is 100-300mls of blood in drain or if not exact volume qualifies with (a lot, significant amount, unusual amount, quite a bit) AND/OR states blood in ileostomy bag no qualification needed.</i>			
17	S	States the situation <i>Her urinary output 20mls/hr</i>			
18	S	States the situation States patient is on IV fluids			
19	B	Background information <i>States she has history of Crohn's disease states history</i>			
20	B	Background information <i>States she is two days post laparotomy/ileostomy/bowel resection</i>			
21	B	Irrelevant background <i>States fractured humerus two years ago</i>			
22	A	Assessment <i>Gives relevant case specific assessment</i>			
23	A	Assessment <i>I think she is bleeding</i> +/- patient is hypovolemic			
24	R	Seeks a recommendation from recipient <i>Do you want me to do anything else/what else would you recommend?</i>			
25	R	Omits to "repeat back" <i>You would like me to give her a fluid bolus of 500mls and the time frame agreed for review</i> <i>[eg: straight away/ in 30 minutes]</i>			
26	R	Uses own notes and/or an ISBAR sticker to aid phone call			
27		Length of call [seconds]	secs		
			no. of steps = no. of boxes checked	no. of errors = no. of boxes checked	no. of critical errors = no. of boxes NOT checked
TOTALS					
Proficiency Benchmark		Proficiency Demonstrated [tick box]	Observer's Initial		
<ul style="list-style-type: none"> Steps ≥ 6 No more than 4 Errors, 3 of which may be critical 		<input type="checkbox"/> YES <input type="checkbox"/> NO			



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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

1			
2		assessing outcomes) and how	
3			
4		11b If relevant, description of the similarity of interventions	8/9/10/11
5	Statistical methods	12a Statistical methods used to compare groups for primary and secondary outcomes	15
6		12b Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
7			
8	Results		
9	Participant flow (a	13a For each group, the numbers of participants who were randomly assigned, received intended treatment, and	Figure 1
10	diagram is strongly	were analysed for the primary outcome	
11	recommended)	13b For each group, losses and exclusions after randomisation, together with reasons	Figure 1
12	Recruitment	14a Dates defining the periods of recruitment and follow-up	8
13		14b Why the trial ended or was stopped	n/a
14	Baseline data	15 A table showing baseline demographic and clinical characteristics for each group	Table 1
15	Numbers analysed	16 For each group, number of participants (denominator) included in each analysis and whether the analysis was	Figure 1
16		by original assigned groups	
17			
18	Outcomes and	17a For each primary and secondary outcome, results for each group, and the estimated effect size and its	15,16
19	estimation	precision (such as 95% confidence interval)	
20		17b For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
21	Ancillary analyses	18 Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing	n/a
22		pre-specified from exploratory	
23			
24	Harms	19 All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
25			
26	Discussion		
27	Limitations	20 Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
28	Generalisability	21 Generalisability (external validity, applicability) of the trial findings	19
29	Interpretation	22 Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
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31	Other information		
32	Registration	23 Registration number and name of trial registry	ClinicalTrials
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39	Protocol	24 Where the full trial protocol can be accessed, if available	Attached,Clini
40			cal trials.gov,
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4 Funding 25 Sources of funding and other support (such as supply of drugs), role of funders

and attached
none

5
6 *We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also
7 recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials.
8 Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.
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BMJ Open

The effect of a proficiency-based progression simulation programme on clinical communication for the deteriorating patient: A randomised controlled trial.

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2018-025992.R2
Article Type:	Research
Date Submitted by the Author:	13-May-2019
Complete List of Authors:	Breen, Dorothy; Cork University Hospital Group, Department of Anaesthesia and Intensive Care O'Brien, Sinead; University College Cork National University of Ireland, School of Nursing and Midwifery McCarthy, Nora; University College Cork National University of Ireland, Medical Education Unit, School of Medicine Gallagher, Anthony; Ulster University , Faculty of Life and Health Sciences Walshe, Nuala; University College Cork National University of Ireland, School of Nursing and Midwifery
Primary Subject Heading:	Communication
Secondary Subject Heading:	Communication, Medical education and training, Nursing
Keywords:	Handover, Simulation, Safety, Communication, Assessment, Performance

SCHOLARONE™
Manuscripts

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3 The effect of a proficiency-based progression simulation programme
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6 on clinical communication for the deteriorating patient: A
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8 randomised controlled trial.
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52 Word Count: 4,394 including abstract

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55 Key words: Medical Education and Training, Handover, Simulation,
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8 randomised controlled trial.
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14 **ABSTRACT**

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17 **Objective**

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19 To determine the effectiveness of a proficiency-based progression
20 training approach to clinical communication in the context of a
21 clinically deteriorating patient.
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28 **Design**

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30 A randomised controlled trial with three parallel arms.
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33 **Setting**

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35 A university setting in Ireland
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38 **Participants**

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40 45 third year nursing and 45 final year medical undergraduates
41 scheduled to undertake interdisciplinary National Early Warning
42 Score (NEWS) training over a three day period in September 2016.
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49 **Interventions**

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51 Participants were prospectively randomised to one of three groups
52 before undertaking a performance assessment of the ISBAR
53 communication tool (Identification, Situation, Background,
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3 Assessment, Recommendation) relevant to a deteriorating patient in
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6 a high fidelity simulation facility. The groups were as follows (i) E;
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8 the Irish Health Service national NEWS e-learning programme only,
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11 (ii) E+S; the national e-learning programme plus standard
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14 simulation, and (iii) E+PBP; the national e-learning programme plus
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17 proficiency-based progression simulation.
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19 20 Main outcome measures

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22 The primary outcome was the proportion in each group reaching a
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24 pre-defined proficiency benchmark comprising a series of pre-
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26 defined steps, errors and critical errors during the performance of a
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28 standardised, high fidelity simulation assessment case which was
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30 recorded and scored by two independent blinded assessors.
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35 36 Results

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38 6.9% (2/29) of the E group and 13% (3/23) of the E+S group
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40 demonstrated proficiency in comparison to 60% (15/25) of the
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42 E+PBP group. The difference between the E and the E+S groups was
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44 not statistically significant (Chi-Square = 0.55, 99%, CI =0.63-0.66, p=
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46 0.63) but was significant for the difference between the E and the E
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48 +PBP groups (Chi-Square = 22.25, CI=0.00-0.00, p < 0.000) and
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50 between the E+S and the E+PBP groups (Chi-Square = 11.04, CI=0.00-
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52 0.00, p = 0.001).
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Conclusions

Proficiency-based progression is a more effective way to teach clinical communication in the context of the deteriorating patient than e-learning either alone or in combination with standard simulation.

Trial Registration

ClinicalTrials.gov Identifier: NCT02886754

STRENGTHS AND LIMITATIONS OF THE STUDY

- This is the first randomised controlled trial of a proficiency-based progression educational intervention for a non-technical skill.
- The performance outcomes are robust objective measurements which do not rely on subjective assessments or learner perceptions.
- Limitations are the single centre design and the future need for the impact of proficiency-based progression programmes on patient outcomes.

Funding Statement: This research received no specific grant from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests: All authors have completed the ICMJE uniform

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2
3 disclosure form at www.icmje.org/coi_disclosure.pdf and declare: no
4
5
6 support from any organisation for the submitted work, no financial
7
8
9 relationships with any organisations that might have an interest in
10
11
12 the submitted work in the previous three years; no other
13
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15 relationships or activities that could appear to have influenced the
16
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18 submitted work.

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22 Ethical Approval: Institutional review board approval was obtained.
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25 Informed written consent was obtained from all participants.
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31 Transparency: The lead author affirms that the manuscript is an
32
33
34 honest, accurate and transparent account of the study being
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37 reported; that no important aspects have been omitted; and that any
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40 discrepancies from the study as planned have been explained.
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22 All authors listed below met ICMJE criteria for contributorship as
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24 outlined below.
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32 the acquisition, of the data for the work; AND
33
34
35 2. Drafting the work, revising the work critically for important
36
37 intellectual content AND
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40 3. Drafting the final version to be published; AND
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43 4. Agrees to be accountable for all aspects of the work in ensuring
44
45 that questions related to the accuracy or integrity of any part of the
46
47 work are appropriately investigated and resolved.
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11 that questions related to the accuracy or integrity of any part of the
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22 work; and the acquisition, AND
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50 2. Revising the work critically for important intellectual content;
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3 to ensure that questions related to the accuracy or integrity of any
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11 1. Contributed substantially to the conception and design of the
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13 work; and the acquisition, of data for the work; AND
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16 2. Revising the work critically for important intellectual content;
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22 3. Final approval of the version to be published; AND
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25 4. Agrees to be accountable for all aspects of the work in ensuring
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29 work are appropriately investigated and resolved.
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36 Data Sharing: Deidentified individual participant data that underlie
37
38 the results published in this article as well as study protocol,
39
40 statistical analysis plan and analytical code will be made available on
41
42 request beginning three months and ending 5 years after publication
43
44 to researchers who provide a methodologically sound proposal.
45
46 Please direct requests to the corresponding author. Data accessors
47
48 will need to sign a data access agreement. The data from the pilot
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50 study and from this study in relation to learner perceptions is
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52 undergoing analysis and will be available following publication.
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Introduction

Simulation-based training is being increasingly deployed for both technical and non-technical skill acquisition in healthcare with the aim of reducing medical error and patient harm. There is a need for an evidence-based approach to such training to ensure that the resources utilised can reliably deliver a quantifiable improved skill set rather than just an enhanced educational experience. Proficiency-based progression (PBP) training is a form of outcomes-based training that involves training individuals to achieve a proficiency benchmark. The process involves “deliberate” practice against a set of clearly defined objective metrics. The proficiency benchmark is set as the mean performance of clinicians who undertake the procedure regularly in clinical practice. It has been shown to improve the performance of individuals undertaking technical procedures^{1, 2, 3, 4, 5, 6, 7}. Metrics are operationally defined to facilitate objective scoring. For example in the study by Cates et al demonstrating improved performance of carotid angiography, pre-defined metric errors include “number of diagnostic catheters used to obtain diagnostic pictures” and “catheter advancing without a guide-wire in front of it”⁶. Despite these results, PBP methodology has not previously been

1
2
3 applied to simulation-based training for non-technical skills yet
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5
6 communication failures are a significant source of medical error and
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8
9 preventable adverse events equal if not greater than errors due to
10
11 lack of technical skill ^{8, 9, 10}. Escalation of care for an acutely
12
13 deteriorating patient demands the most efficient, concise and
14
15 accurate flow of information amongst healthcare workers of different
16
17 disciplines for the best outcome to be achieved.
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23 Early Warning Scores facilitate early detection of deterioration by
24
25 categorising a patient's severity of illness and prompting escalation
26
27 of care at specific trigger points utilising a structured communication
28
29 tool such as ISBAR (Identification, Situation, Background,
30
31 Assessment, Recommendation). This enables a more timely response
32
33 using a common language ¹¹. Ireland was one of the first countries to
34
35 agree and implement a standardised Early Warning Score (The
36
37 National Early Warning Score, NEWS) across the entire acute hospital
38
39 sector. NEWS utilises the ISBAR tool as the recommended structured
40
41 communication tool for the acutely deteriorating patient ^{12, 13}. The
42
43 National Early Warning Score (NEWS) e-learning education
44
45 programme is recommended as the national interdisciplinary
46
47 education programme for all healthcare professionals working in
48
49 acute services. The programme teaches ISBAR as the standardised
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3 tool to escalate care in the context of the acutely deteriorating
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6 patient.
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10 The primary aim of this study was to determine if the addition of a
11
12 proficiency-based progression simulation training programme to the
13
14 national NEWS e-learning module results in better performance of
15
16 clinical communication of a deteriorating patient than either the e-
17
18 learning module alone or in combination with standard simulation.
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Methods

Study design

A randomised controlled trial with three parallel arms.

Participants

Eligible participants were 109 third year nursing and 201 final year medical students who were scheduled to undertake interdisciplinary National Early Warning Score training in September 2016 as part of their undergraduate curriculum. This comprised the entire undergraduate nursing and medical classes except for 31 medical students who were scheduled to undertake this training at a later time in the curriculum (figure 1).

Interventions

1
2
3 All 3rd year nursing and final year medical students were emailed
4
5
6 prior to training and instructed to undertake the National Early
7
8
9 Warning Score e-learning programme. Written informed consent
10
11 was obtained from all participants. On the day of training,
12
13
14 participants were required to submit a certificate of successful
15
16
17 completion of the e-learning programme. A 15-minute lecture on the
18
19
20 ISBAR tool was delivered before participants undertook training as
21
22
23 per their allocated groups. Students were not notified as to which
24
25
26 study group they were allocated. The study flow is outlined in figure
27
28
29
30 2.

31 The three training groups were as follows:

32
33 **(i) e-learning only group (E).** Participants in this group proceeded
34
35 immediately following the 15-minute lecture to the high fidelity suite
36
37 for performance assessment. After outcome assessment was
38
39 complete, participants undertook simulation training similar to the
40
41
42 E+S group as outlined below in order to ensure that all students were
43
44
45 afforded the same training opportunity from a curriculum
46
47
48 perspective.
49
50

51
52 **(ii) e-learning plus standard simulation group (E+S).** Participants
53
54 worked in pairs of a medical student and nursing student. If a
55
56
57 participant did not have a partner, then a non-study peer student was
58
59
60

1
2
3 asked to pair with that individual for the purposes of training. Data
4
5
6 from the non-study student was not included in the analysis.
7

8
9 Training consisted of a series of simulated phone calls using four
10
11 standardised paper cases for each discipline. Case materials included
12
13 case notes, NEWS charts, and a blank ISBAR template indicating the
14
15 categories and type of information that should be communicated.
16
17 Each scenario had a deteriorating patient event that necessitated an
18
19 ISBAR telephone communication. Participants alternated between
20
21 making and receiving simulated phone calls. A standardised script
22
23 was given to the recipient. Two facilitators conducted the simulation
24
25 training. Both facilitators were experienced clinicians and educators
26
27 who had previously undergone the “Train the Trainer NEWS
28
29 programme” and regularly facilitate NEWS training and healthcare
30
31 simulation. The facilitators offered support and feedback in line with
32
33 standard NEWS training by listening to simulated phone calls and
34
35 offering guidance on the ISBAR framework and by answering
36
37 questions as they arose. Participants were required to work through
38
39 all four cases with their partner. Towards the end of the training
40
41 session the participants presented to the facilitator to repeat a
42
43 simulated phone call for either case 3 or 4. The training session was
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58 3.5 hours in duration, participants were required to stay until the end
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3 of the training regardless of progress. If an individual had completed
4
5 all the cases, they were asked to assist by continuing to be the
6
7 recipient of phone calls for their partner or by continuing to practice
8
9 by repeating the cases if required.
10
11
12

13
14 **(iii) e-learning plus proficiency-based progression simulation**

15
16 **group (E+PBP).** Participants underwent a training programme of
17
18 the same structure, duration (3.5 hours), content and facilitator:
19
20 student ratio as the E+S group. The same two facilitators facilitated
21
22 both the E+S and E+PBP training. However in the E+PBP group,
23
24 partners scored each other's phone calls during training against a
25
26 series of pre-defined metrics (quantified as steps, errors and critical
27
28 errors for each case) on a score sheet to ascertain if the proficiency
29
30 benchmark for that case was reached. Partners shared the results of
31
32 the metrics and proficiency scores with each other as feedback at the
33
34 end of each simulated phone call. If proficiency was not achieved the
35
36 case was repeated before progressing to the next case. Participants
37
38 were required to reach proficiency on all four cases with their
39
40 partner before performing case 3 or 4 with the facilitator and
41
42 demonstrating proficiency again. If proficiency was not achieved with
43
44 the facilitator then the participant returned to repeat cases with their
45
46 partner and present for reassessment to the facilitator until
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3 proficiency was demonstrated. The training session was 3.5 hours in
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5 duration, participants were required to stay until the end of the
6
7 training regardless of progress. If an individual had completed all the
8
9 cases, they were asked to assist by continuing to be the recipient of
10
11 phone calls for their partner or by continuing to practice by repeating
12
13 the cases if required.
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23 **Outcomes**

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27 The primary outcome was the ability to reach the proficiency
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29 benchmark on the standardised high-fidelity simulation assessment
30
31 case. The secondary outcomes were the number of successfully
32
33 completed steps, errors and critical errors performed by each group.
34
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36
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39
40 Performance metrics were developed for the training cases and for
41
42 the high fidelity simulation assessment case as part of a pilot study in
43
44 the previous year. Each case presented a different but commonly
45
46 encountered clinical scenario of an acutely deteriorating patient. As
47
48 an example, the outline of the nursing component of the high fidelity
49
50 simulation assessment case is shown in figure 3.
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3 The metrics were derived for each of the training and assessment
4 cases according to the 5 components of the ISBAR tool and were
5 specific to each case.
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12 The performance metrics were validated through a modified Delphi
13 expert panel consisting of 9 senior nurses and 8 medical staff who
14 regularly facilitate NEWS/ISBAR communication training. Delphi
15 panel members reviewed the performance metric for each of the
16 simulation cases and the high fidelity performance outcome case and
17 metric units were included, excluded or modified by consensus. Each
18 metric unit was then classified as a step, error or critical error by
19 consensus. The majority of metrics were common to both medicine
20 and nursing. The number of metrics per case ranged from 24-26.
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37 The proficiency benchmark was set as the mean performance of
38 qualified personnel from the respective disciplines on each case. Nine
39 nursing and five medically qualified practitioners (who regularly
40 escalate care in the acute healthcare setting and with a mean years of
41 experience=3 years) underwent the high fidelity simulation case. The
42 proficiency benchmark for the assessment case was set as the mean
43 performance for each discipline as scored by two independent
44 assessors using the pre-defined metrics. An extract from the metric
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3 scoring sheet and proficiency benchmark for the high fidelity
4 simulation assessment case is shown in figure 4.
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7
8 Digital recordings of each participant's performance of the
9 standardised case in the high fidelity assessment suite were
10 reviewed and scored by two independent assessors (experienced
11 acute care nurses) using the pre-defined metrics and proficiency
12 benchmark.
13
14

15
16 The assessors underwent training on scoring the material using 10
17 recordings of the same case obtained from non-study participants.
18 Assessment of the digital recordings was undertaken within 2
19 months of study participation. An inter-rater reliability of > 85% was
20 achieved prior to commencing scoring study material. The assessors
21 were not part of the investigator group, were blinded to the study
22 group allocations and had no prior knowledge of any of the
23 participants.
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47 **Sample size**

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49 Power calculation: the numbers needed in each arm was based on
50 transfer of training (the degree to which trainees transfer the
51 knowledge and skills acquired from one learning situation to another
52 setting) observed in previous studies of proficiency based
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3 progression simulation in surgery and cardiology, where transfer of
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5 training rates of 42-69% have been observed ^{1, 2, 3, 4, 5, 6}. In a pilot for
6
7 the current study on 133 medical and nursing students in the
8
9 previous academic year, the transfer of training rate was observed to
10
11 be 16% for the proficiency based training group and 3% for the
12
13 standard simulation group. The pilot however was constrained by
14
15 the existing curriculum, which only allowed for 90 minutes training
16
17 time once the e-learning programme was complete. In the current
18
19 study a longer training time (3.5 hours) and a more rigorous
20
21 structure was facilitated. We therefore expected to observe an
22
23 increase in transfer of training to >40% based on a 3 fold increase in
24
25 objective, blind, assessment of proficiency when compared to the
26
27 control group (i.e. 9% for the E group vs. 49% for the E+PBP group).
28
29 A two-tailed test, with n=20 trainees in each group with an alpha of
30
31 5% (which corresponds to a 95% confidence interval) would yield a
32
33 statistical power of 89.9. Therefore 30 (15 medical and 15 nursing
34
35 students) were randomised to each group to allow for drop out rates
36
37 observed in the pilot due to students rescheduling to non-study
38
39 training dates as a result of conflicting demands of their curriculum.
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55 **Randomisation and blinding**

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3 A de-identified numbered list of nursing and medical student
4 numbers was obtained from the School of Nursing and Midwifery and
5
6 the School of Medicine. The lists comprised 109 third year nursing
7
8 and 201 final year medical students scheduled to complete an
9
10 interdisciplinary ISBAR training programme as part of the University
11
12 undergraduate curriculum in September 2016. Randomisation was
13
14 stratified by discipline and was conducted using a computer-
15
16 generated programme (GraphPad QuickCals software package,
17
18 www.graphpad.com/quickcalcs/) as a two-stage process (figure 1).
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28 Firstly n=45 nursing and n=45 medical students were randomly
29
30 selected using the programme. These 90 students were then
31
32 randomly allocated by discipline using the same computer
33
34 programme to one of the three training groups: E, E+S, and E+PBP.
35
36 Subjects were excluded from the study if: (i) a certificate of
37
38 successful completion (within the previous 4 weeks) of the National
39
40 Early Warning Score (NEWS) e-learning education programme was
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42 not presented on the day of training, (ii) lack of consent.
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52 **Statistical analysis**

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55 Statistical Analysis was performed with SPSS 22 (Armonk, New
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57 York). The Kruskal-Wallis test was used to determine if there was a
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3 statistical difference between groups in relation to the primary end
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6 point (the numbers reaching proficiency) and the secondary end
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9 points (the number of completed steps, errors and critical errors).
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11 The relationship of the three training programmes on proficiency
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13
14 was explored using logistic regression analysis.
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16

17 Patient and Public Involvement

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19
20 Patients were not involved in the design or conduct of the study.
21
22

23 Results

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26 Baseline characteristics with respect to age, gender, discipline,
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29 nationality and first language of the participants in each group are
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32 shown in table 1.
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Table 1

Study Group		E	E+S	E+PBP	Total
		n=30	n=30	n=30	n=90
Discipline	Nursing (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
	Medicine (%)	15 (50.0%)	15 (50.0%)	15 (50.0%)	45 (50.0%)
Age Group	18-23 years (%)	21 (70.0%)	19 (63.3%)	20 (66.7%)	60 (66.7%)
	24-29 years (%)	7 (23.3%)	8 (26.7%)	9 (30.0%)	24 (26.7%)
	>30 years (%)	2 (6.7%)	3 (10.0%)	1 (3.3%)	6 (6.7%)
Gender	Male (%)	6 (20.0%)	5 (16.7%)	6 (20.0%)	17 (18.9%)
	Female (%)	24 (80.0%)	22 (83.3%)	24 (80.0%)	73 (81.1%)
Nationality	Irish (%)	22 (73.3%)	24 (80.0%)	21 (70.0%)	67 (74.4%)
	Non-Irish (%)	8 (26.7%)	6 (20.0%)	9 (30.0%)	23 (25.6%)
First Language	English (%)	25 (83.3%)	22 (73.3%)	19 (63.3%)	66 (73.3%)
	Other (%)	5 (16.7%)	4 (13.3%)	7 (23.3%)	16 (17.8%)
	Not available (%)	-	4 (13.3%)	4 (13.3%)	8 (8.9%)

Figure 5 shows percentages of participants in each group who demonstrated the proficiency benchmark following assessment in

1
2
3 the high fidelity simulation suite. At the end of training, 6.9% (2/29)
4
5 of the e-learning only (E) group and 13 % (3/23) of the standard
6
7 simulation (E+S) group demonstrated proficiency. In comparison
8
9 60% (15/25) of proficiency-based progression simulation (E+PBP)
10
11 group were proficient. The difference between the E group and the
12
13 E+S group was not statistically significant (Chi-Square = 0.55, 99%, CI
14
15 =0.63-0.66, p= 0.63) but was significant for the difference between E
16
17 group and the E +PBP group (Chi-Square = 22.25, CI=0.00-0.00, p <
18
19 0.000) and between the E+S group and the E+PBP group (Chi-Square
20
21 = 11.04, CI=0.00-0.00, p = 0.001).

22
23 On logistic regression analysis (figure 6) it was found that in
24
25 comparison to the E group, the E+PBP trained group were more than
26
27 20 times as likely to demonstrate proficiency and the difference was
28
29 statistically significant (Ext (B) =20.25, 95% CI=3.91-105, p<0.000).

30
31 The E+PBP group completed significantly more steps, mean 8.5 (1.7)
32
33 than either the E, mean 5.8 (1.6), p<0.000 or E+S groups, mean 6.3
34
35 (2.1), p<0.000 group. Similarly, combined errors and critical errors
36
37 were significantly less in the E+PBP, mean 3.7 (1.6) than either the E,
38
39 mean 5.9 (2.1), p<0.000 or the E+S groups, mean 5.2 (1.5), p<0.01
40
41 group. Inter-rater reliability of the two assessors was 97%.

Discussion

Our results show that addition of a proficiency-based progression simulation programme to an e-learning module can deliver a superior set of skills for ISBAR communication in relation to a deteriorating patient than an e-learning module either alone or in combination with standard simulation. Furthermore this benefit is seen within the same resources i.e. materials, timeframe, and facilitators as standard simulation. The Irish health service like its international counterparts has prioritised clinical communication as a key part of the patient safety agenda ^{12, 13, 14, 15, 16}. Clinical communication is now viewed as an essential skill and training is recommended as mandatory for all health and social care professionals ¹³. All participants were required to produce a recent certificate of successful completion of the e-learning programme but only 6.9% of the group who undertook the e-learning module only demonstrated the proficiency benchmark. The addition of standard simulation did not significantly improve performance with only 13% of the E+S group reaching the benchmark.

It could be argued that exposure to metrics-based scoring in the practice cases resulted in better performance in the assessment case

1
2
3 for the E+PBP group. However this is precisely the desired effect i.e.
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5
6 that trainees know what skills need to be achieved, practice to
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8
9 achieve them to an objective pre-defined standard and transfer that
10
11 training to a dynamic scenario. The E+S and E+PBP groups differed in
12
13 only two respects: (i) practice was “repeated” in the E+S cohort as
14
15 opposed to “deliberate” in E+PBP cohort i.e. focused on pre-defined
16
17 metrics and (ii) the E+PBP group was required to reach proficiency
18
19 benchmarks to progress through simulation cases whereas the E+S
20
21 group were not. Our results demonstrate that proficiency-based
22
23 training can achieve skill acquisition rates of the order of 60%,
24
25 similar to those seen with technical skills using this approach. In a
26
27 study of similar experimental design, Angelo et al found that there
28
29 were 56% fewer intraoperative errors and 69% fewer critical errors
30
31 when compared to traditional training². To our knowledge our study
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33 is the first randomised trial of proficiency-based progression training
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35 of a non-technical skill.
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47 The main strength of the study is the use of robust methodology to
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49 determine the effectiveness of an educational intervention on
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51 objectively assessed performance outcomes. The study combines the
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53 rigour of a randomised controlled trial with that of an outcomes
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55 based- training approach (proficiency-based progression) to clinical
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3 communication. A significant body of evidence already exists in
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5
6 relation to the use of proficiency-based progression for technical skill
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8
9 acquisition ^{7, 8, 9, 10, 11, 12, 13}. Our results support the use of proficiency-
10
11
12 based progression training for communication skills also.

13
14 Weaknesses of the study include the single centre design and the
15
16 application to the undergraduate population only, although the
17
18 training programme was designed for qualified nurses and doctors
19
20 also. Since the completion of study, the programme has been applied
21
22 successfully to both nursing and medical undergraduate programmes
23
24 in the university setting and to doctors in training in the hospital
25
26 setting. There is a need for future research on the application of the
27
28 programme in different clinical settings and its impact on patient
29
30 outcomes.
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39 The study was limited by the restriction on training time. The
40
41 duration of simulation training for both E+S and the E+PBP groups
42
43 was extended to 3.5 hours from the initial pilot (1.5 hours), but was
44
45 still restricted by the existing undergraduate curriculum rather than
46
47 that which would ideally be required to train a fundamental skill.
48
49
50 Skills consolidation is an important part of the learning process
51
52 particularly for new skills ¹⁷. In the study by Angelo et al. ² trainees
53
54 had a weekend in which to acquire, refine and consolidate their skills
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3 before their proficiency assessment at the end of training. Another
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6 difficulty, which may have impinged on the effectiveness of training,
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9 was the disparity in fidelity between the paper-based training
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12 environment and the assessment undertaken in the high fidelity
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15 simulation environment. This disparity is challenging for those with
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18 limited clinical experience such as the undergraduate population.
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20 Van Sickle et al ³ and Gallagher et al ⁴ have commented on the
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23 detrimental impact that this disparity can have on proficiency
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26 demonstration by trainees.

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28 It is now widely recognised that clinical communication skills
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31 underpin patient safety. Implementation of a training programme in
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34 relation to clinical communication has already been shown to reduce
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37 medical error and preventable adverse events ¹⁸. There is a need for
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40 valid, reliable, cost efficient clinical communication training
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43 programmes to address this need and the impact on patient as well
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46 as healthcare provider outcomes.

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48 In summary, our study shows that proficiency-based progression is a
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51 more effective way to teach clinical communication for the
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54 deteriorating patient than e-learning either alone or in combination
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57 with standard simulation. Furthermore, improved performance with
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60 proficiency-based progression simulation was achieved with the

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3 same training time and facilitator/student ratio as standard
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6 simulation.
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Legends

Table 1. Demographic characteristics of the three study groups: e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) .

Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training

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2
3 groups (E, E+S, E+PBP) of undergraduate medical and nursing
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6 participants.
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11 Figure 3. Outline of the high fidelity simulation performance
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14 assessment case for nursing undergraduates
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20 Figure 4. Extract from the nursing metric scoring sheet illustrating
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22 some of the metrics and the proficiency benchmark for the high
23
24 fidelity simulation assessment case.
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30 Figure 5. The percentages reaching the proficiency benchmark at the
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32 end of training of the three study training groups; e-learning alone
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34 (E), e-learning plus standard simulation training (E+S) and e-learning
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36 plus proficiency-based progression simulation training (E+PBP).
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44 Figure 6. Logistic regression analysis for the relative differences
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47 between the three study training groups of undergraduate medical
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49 and nursing participants; E, E+S and E+PBP.
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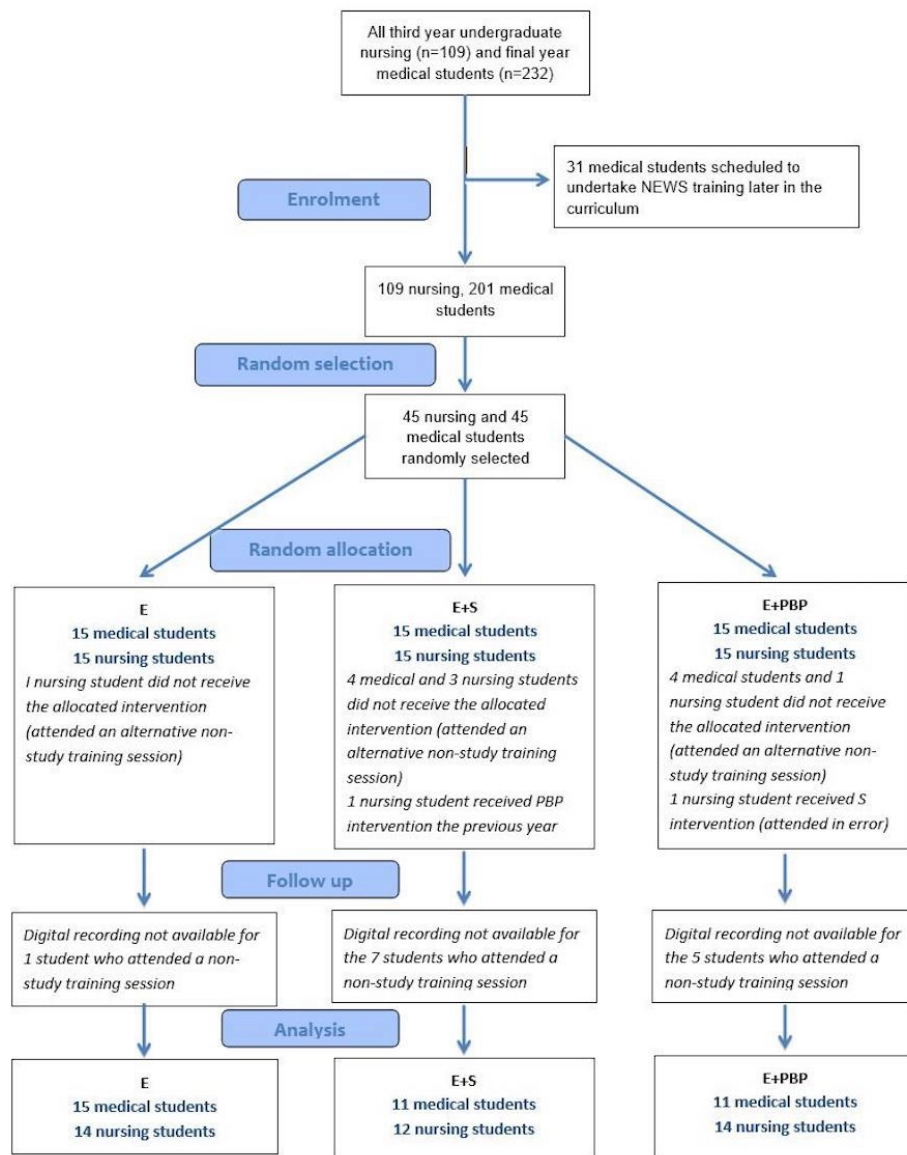


Figure 1. Consort diagram outlining selection, allocation and follow up of undergraduate medical and nursing participants in a study comparing the effect of e-learning alone (E), e-learning plus standard simulation (E+S) and e-learning plus proficiency-based progression simulation (E+PBP) on clinical communication.

76x98mm (300 x 300 DPI)

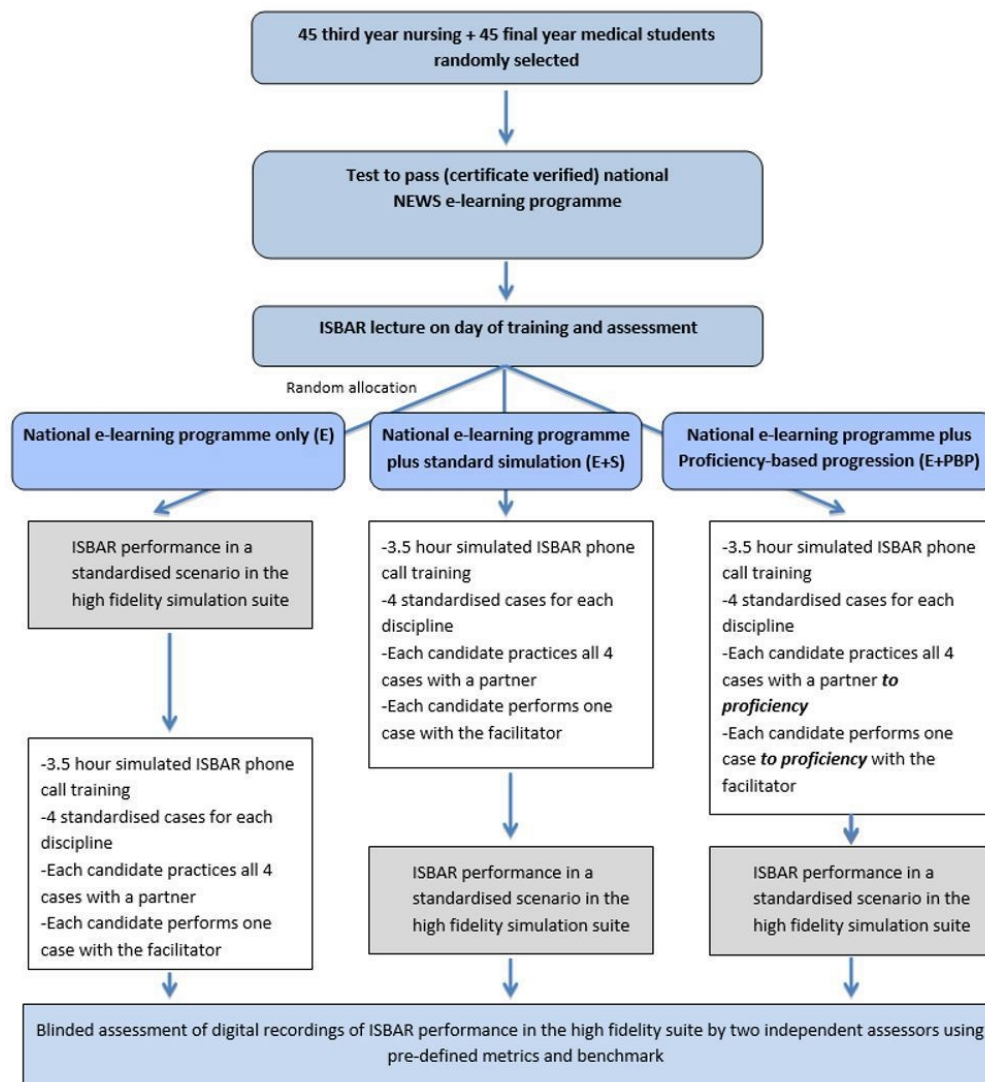


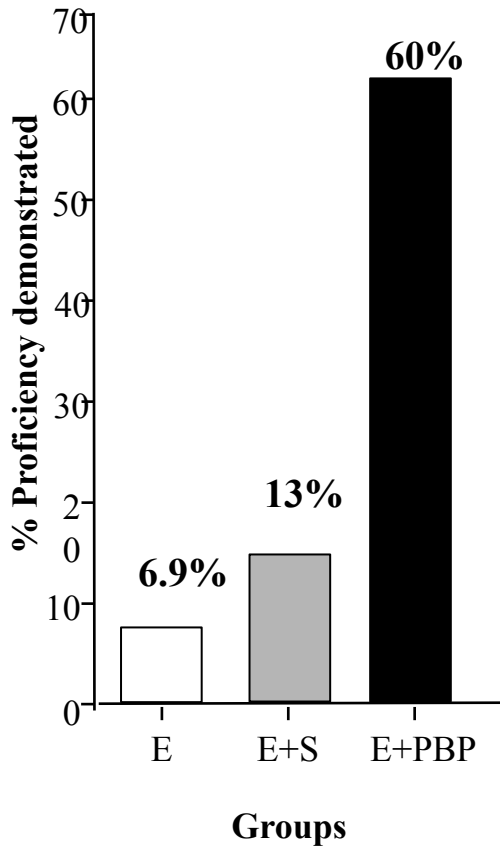
Figure 2. Outline of experimental design and study flow indicating training interventions and assessment of the three study training groups (E, E+S, E+PBP) of undergraduate medical and nursing participants.

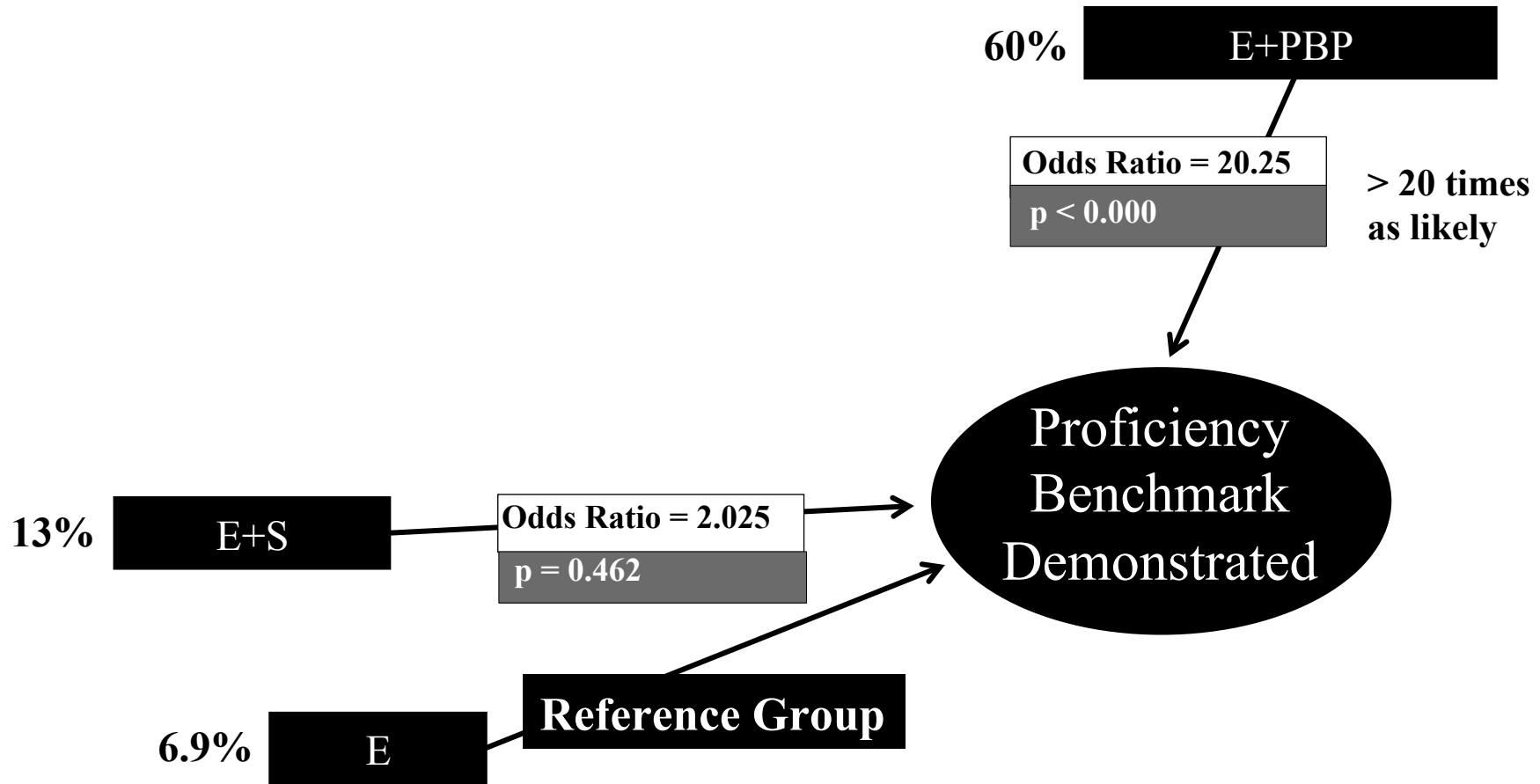
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Simulator Parameters		Roleplayer vocals	Escalation Call	
2	RR	21	2 days post laparotomy	
3	SpO ₂	96%	you feel very tired and weak	
4	oxygen	Room Air	you think you should be feeling better than you are	
5	BP	92/58	Do not ask any questions or provide any information throughout this phone-call except to answer the below questions	
6	HR	98	you thought you would be improving at this stage	
7	AVPU	Alert	if asked you feel your pain is less controlled than yesterday	
8	Temp	36.7	you are still nil by mouth	
9	EWS	5	you now have a temporary ileostomy and are a quite upset about this, but know it will hopefully be reversed in the future	
10	Cardiac monitor	Sinus tachycardia (if attached to CM)		
11	Cap refill	less than 2sec		
12	skin	pink, warm, dry		
13	Urinary output (0.5ml/kg/hr)	20mls last hour	If recipient name not confirmed, and you are asked "is this the intern/SHO/reg?"	
14	IV site	VIP = 0 [visual infusion phlebitis score]	If asked for any recommendation	
15	IV hydration	125mls/hr	If told "I think she is bleeding/needs review/has sepsis"	
16	Pain	Student to assess if asked for PCA - 32mls in syringe; 35 demands, 18 successful]	If asked "Will you review her?"	
17	Bowel sounds	Student to assess absent	If asked "When will you review her?"	
18	Abdomen	wound - assess independently drain assess independently ileostomy : assess independently distension yes abdomen is distended	If told "Her EWS is (3-7), so you must review her in 30mins"	
19	Blood Loss	If students enquire requiring volume in drain/ileostomy - say "you may assess independently" If students pick up a jug to empty either give them the relevant volume " there are 250mls in the drain " " there are 100mls in the ileostomy "	If asked "Will you review her in 30 minutes/straight away?"	
20	Chest sounds	normal		
21	Cap blood sugar	5.8mmol/L		

Extract from Nursing Simulation Metric					
			Tick if present	Tick if present	Tick if present
16	S	States the situation <i>There is 100-300mls of blood in drain or if not exact volume qualifies with (a lot, significant amount, unusual amount, quite a bit) AND/OR states blood in ileostomy bag no qualification needed.</i>			
17	S	States the situation <i>Her urinary output 20mls/hr</i>			
18	S	States the situation States patient is on IV fluids			
19	B	Background information <i>States she has history of Crohn's disease states history</i>			
20	B	Background information <i>States she is two days post laparotomy/ileostomy/bowel resection</i>			
21	B	Irrelevant background <i>States fractured humerus two years ago</i>			
22	A	Assessment <i>Gives relevant case specific assessment</i>			
23	A	Assessment <i>I think she is bleeding</i> +/- patient is hypovolemic			
24	R	Seeks a recommendation from recipient <i>Do you want me to do anything else/what else would you recommend?</i>			
25	R	Omits to "repeat back" <i>You would like me to give her a fluid bolus of 500mls and the time frame agreed for review</i> <i>[eg: straight away/ in 30 minutes]</i>			
26	R	Uses own notes and/or an ISBAR sticker to aid phone call			
27		Length of call [seconds]	secs		
			no. of steps = no. of boxes checked	no. of errors = no. of boxes checked	no. of critical errors = no. of boxes NOT checked
TOTALS					
Proficiency Benchmark		Proficiency Demonstrated [tick box]	Observer's Initial		
<ul style="list-style-type: none"> Steps ≥ 6 No more than 4 Errors, 3 of which may be critical 		<input type="checkbox"/> YES <input type="checkbox"/> NO			

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CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1-3
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	5
	2b	Specific objectives or hypotheses	7
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n/a
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8/9/10/11 Figure 2
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11 and 5 protocol
	6b	Any changes to trial outcomes after the trial commenced, with reasons	n/a
Sample size	7a	How sample size was determined	13
	7b	When applicable, explanation of any interim analyses and stopping guidelines	n/a
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	14
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	14
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	14
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	2/3 protocol
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	14, 15

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	8/9/10/11
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	15
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	n/a
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	8
	14b	Why the trial ended or was stopped	n/a
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Figure 1
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	15,16
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	15,16
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	n/a
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	n/a
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	15/16
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	19
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19
Other information			
Registration	23	Registration number and name of trial registry	ClinicalTrials.gov NCT02886754
Protocol	24	Where the full trial protocol can be accessed, if available	Attached, Clinical trials.gov,

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and attached
none

Funding 25 Sources of funding and other support (such as supply of drugs), role of funders

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

For peer review only